Monday 22 January 2018

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SUBMISSION TO THE SENATE INQUIRY INTO HEALTH SERVICES RED TAPE

The Medical Oncology Group of Australia (MOGA) is the national professional organisation for medical oncology and members of the profession. MOGA is a speciality society of the Royal Australasian College of Physicians and represents 660 members in Australia and New Zealand.

The Association welcomed the announcement on 11 October 2016 that the Senate had resolved to establish the Select Committee on Red Tape to inquire into the effect of restrictions and prohibitions on business on the economy and community for Health Services. Red Tape has an important role to play in determining due process and ensuring appropriate safeguards are in place nationally, but can and does adversely impact on many areas of Australian medical and health care services, including the diagnosis, treatment and management of cancer. MOGA seeks to promote best practice standards in all areas of care for Australian patients and to ensure that our patients have access to timely and affordable, quality medical care. Cancer is a leading cause of death in Australia. An estimated 134,000 new cases of cancer will be diagnosed in Australia this year, with that number set to rise to 150,000 by 2020. Given the growing cancer burden reducing the red tape in health and medical services is a priority.

The Association presents the following advice for consideration in response to the Terms of Reference:

1. **the effects on compliance costs (in hours and money), economic output, employment and government revenue;**

The Association is of the view that the costs of compliance for Australian medical oncologists, especially those working in the private sector is considerable and represents a major administrative time and expense burden. Eg., see that attached correspondence dated 25 January 2017 to Professor Andrew Wilson Chair, Pharmaceutical Benefits Advisory Committee (PBAC) regarding administrative and procedural barriers and impediments to the prescribing of Pharmaceutical Benefits Schedule (PBS) listed oncology drugs that are of major concern to members of the Australian medical oncology profession.These barriers and limitations impact

negatively on the effective and efficient delivery of medical services to Australian oncology patients; and place an unnecessary administrative burden on Australian medical oncology clinicians. In many cases we believe that these barriers and impediments are the result of administrative requirements and processes that have been developed to provide a systematic approach for governmental and regulatory agencies. However, the Association recommends that immediate consideration be given to implementing more cost effective and efficient administrative processes, including the use of digital communications and approval processes, such as e-prescribing.

2. **any specific areas of red tape that are particularly burdensome, complex, redundant or duplicated across jurisdictions;**

MOGA is of the view that there are significant national disparities between public and private medical oncology service For instance, Australian patients face rising out-of-pocket costs and longer waiting times due to significant financial and regulatory pressures on private practices. Implementations are required to ensure a level playing field applies to the provision and funding of services across the public and private sectors.

3. **the impact on health, safety and economic opportunity, particularly for the low-skilled and disadvantaged;**

Financial toxicity is a well-documented phenomenon and a known adverse outcome for Australian oncology patients. Out of pocket expenses, which are often difficult to assess upfront, being one of the major sources of concern for patients, often exacerbating their condition and directly impacting on their ability to affordably access appropriate services and support. Red tape also impacts negatively on Australian cancer patients in areas including accessing Superannuation, Social Security, Travel assistance and access to some health and medical services. Eg., Addressing the system of making patients pay the whole cost (including the gap) of radiology services upfront. This is a cost burden that may discourage patients from undergoing diagnostic imaging procedures which could compromise their diagnosis and treatment.

4. **the effectiveness of the Abbott, Turnbull and previous governments' efforts to reduce red tape;**

The Association notes the Government's efforts to date to reduce red tape in Australian heath and medical services but would prefer a more timely and less cumbersome approach. For instance, regulatory processes to ensure timely and effective access to oncology drugs and therapies have been revised and expedited pathways have been slowly rolled out over the last few years, but Australian clinicians and patients still do not have timely access to new and emerging options that are available overseas. Both the European and American drugs approval provide good models for how red tape can be reduced while maintaining appropriate national standards of safety and quality for the approval and access to oncology prescription medicines.

5. **alternative institutional arrangements to reduce red tape, including providing subsidies or tax concessions to businesses to achieve outcomes currently achieved through regulation;**

The Association is of the view that the current access and approval system for oncology drugs and treatments in Australia impacts negatively on the delivery and development of clinical trials in Australia. The current barriers posed by the national system have the potential to disengage the medicines industry from Australia and to cause them to divert investment to

other countries. Similarly, delays in securing reimbursement also effects clinical trials, as companies may reconsider placing clinical trials and access programs in Australia if there is little or no chance of reimbursement. The increasing number of special pricing arrangements suggests that the current reimbursement system may not be delivering a fair return on innovation.

The Association strongly supports the reduction of the Australian health services red tape burden and the streamlining of legislative, regulatory and compliance requirements nationally and across all jurisdictions. A major focus should be an integrated national approach to medical service provision. In the first instance, this should focus on data and information requirements which pose a significant administrative burden for medical specialists at both a national and local level. MOGA believes that the Federal government needs to develop a secure national system and infrastructure to manage the digital records of our patients. A common, shared infrastructure for the storage, archiving and retrieval of digital records is recommended. This would assist in addressing delays in patient treatment and management, potential complications and in reducing patient risk nationally. Despite a substantial amount of Federal funding having been committed to Australia's eHealth system a more targeted and comprehensive Government-led approach is needed.

MOGA is of the view that Australia requires a national legislative/regulatory framework which ensures that both private and public sector practices can provide patients across the country with high-quality, safe and affordable services regardless of their geographic location. We urge the Federal Government to fast-track the implementation of the outcomes of this inquiry.

To effectively address the burden of red tape across health and medical services in Australia needs essential input from those on the frontline of providing those services, notably medical specialists. Only in this way will Government be able to introduce changes that will deliver tangible benefits for Australian health services, medical and allied health staff and patients to optimise professional best practice.

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Wednesday 25 January 2017

Professor Andrew Wilson
Chair, Pharmaceutical Benefits Advisory Committee
(PBAC) GPO Box 9848
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ACT 2604

Dear Professor Wilson,

RE: BARRIERS AND IMPEDIMENTS TO PRESCRIBING OF PHARMACEUTICAL BENEFITS SCHEDULE LISTED ONCOLOGY DRUGS

I am writing on behalf of the Medical Oncology Group Australia, the peak national professional organisation for Australian medical oncologists and the profession. As discussed in our Oncology Drugs Working Group Meeting on 25 November, there are a number of administrative and procedural barriers and impediments to the prescribing of Pharmaceutical Benefits Schedule (PBS) listed oncology drugs that are of major concern to members of the Australian medical oncology profession.

We are of the view that these barriers and limitations are impacting negatively on the effective and efficient delivery of medical services to Australian oncology patients; and place an unnecessary administrative burden on Australian medical oncology clinicians. In many cases we believe that these barriers and impediments are the result of administrative requirements and processes that have been developed to provide a systematic approach for governmental and regulatory agencies.
However, the Association recommends that immediate consideration be given to implementing more cost effective and efficient administrative processes, including the use of digital communications and approval processes, such as e-prescribing.

Please find below some key examples of barriers and limitations that have been highlighted by Australian medical oncology clinicians who are members of the Association:

Written approvals

- Clinicians question the requirements for a written application and a two-week waiting period from application to receipt of approval for a prescription for vital high cost medicines where there is a clear clinical urgency. The requirement for written patient consent forms and the need to wait for a stamped original prescription prior to dispensing of these agents is unacceptable given the increasing tardiness and unreliability of regular mail. This is particularly the case for patients in rural and regional areas. Clinicians are of the view that in 2017 a two-week turnaround for the approval and access of any cancer medicine is unacceptable. This delay leads to unnecessary stress and anxiety and may compromise treatment outcomes.

An example of this is the current methods of acquiring HER2 targeted drugs for administration to patients in both adjuvant and metastatic settings in Australia. We believe it is lengthy, overly time consuming and highly distressing for patients, families/carers, clinicians and support staff. Despite sending the paperwork on the day a clinician sees a patient, there is a delay of 2-3 weeks before an approved prescription is returned in the post and can be dispensed.

- In the adjuvant setting the medical oncologist needs to see a patient to obtain a signature, arrange cardiac function testing and receive results, then post forms to Tasmania and receive them back (currently the mail is taking 6 days each way). Despite requests from clinicians the service in Tasmania advises that they are not able to use express post to facilitate rapid return. This situation ensures that the optimal care pathway of commencing adjuvant therapy within 4 weeks of surgery is very difficult for clinicians and patients if they want to commence with an adjuvant non-anthracycline (TCH, APT) HER2 regimen.

- The delay is of particular concern when there is an urgency to commence neoadjuvant treatment for symptomatic locally advanced disease or metastatic disease. It is not acceptable that extremely ill metastatic cancer patients should be forced to wait two weeks to receive access to high priority oncology drugs. At large volume centres based in metropolitan centres medical oncology clinicians are able to treat patients before the prescription is received back from Tasmania if it is clinically indicated and/or dictated. However, this is not feasible at all sites, especially at smaller volume sites such those located in regional, rural or remote centres, and is clearly not optimal.

- Clinicians are concerned that Department staff also alter scripts from a sensibly rounded dose to an actual mg dose and thereby require prescriptions to be changed by the prescribing clinician.

- Another example is the requirement for written rather than phone approval for pazopanib in patients with soft tissue sarcoma, compared to patients who require it for renal cell carcinoma, who can access this drug immediately. Such patients are discriminated against as they are unable to access this drug in a timely fashion. Despite being advised of this anomaly in March 2014 the PBS still require initial prescriptions for this indication to be sent by mail. This bizarre practice impacts very few patients but remains inexplicable discrimination in the view of clinicians treating this disease.

Phone approvals

- The call-in and waiting times for specialised approvals on the 1800 700 270 number are not compatible with clinicians' consulting and work practices nor their working hours. Clinicians are not available to phone and wait on hold on the phone for long periods of time during standard business hours (8am-5pm EST) and it would be highly beneficial if the call-in facility could be available on 24/7 basis.

- The call-in line includes a 94 second introductory recorded message for high cost drugs listing all possible diagnoses and indications and announces 5 options to select from. The

options can only be skipped if you know the correct number in advance and the caller is unable able to return to the start without ending the call and redialling. This recorded message is overly cumbersome and stands as a constant reminder of the unwieldy process that clinicians face when dealing with this system.

- The call-in operators ask a range of questions that are not pertinent or relevant to the request being made and the same questions are repeated for every call in. For instance, clinicians prescribing lenalidomide for myeloma are regularly asked if the patient is on single agent therapy or lenalidomide in combination with dexamethasone when this is of no clinical consequence. Prescribers of lenalidomide for myelodysplasia are repeatedly asked the date of the patients most recent transfusion when given the success of this therapy, this information is unlikely to change for many years. The operators are unable to use the information from prior authority requests during this repetitive process.

- The call-in operators lack appropriate training and briefing. For instance, clinicians are required to spell drug names and guide the operators though the process as these staff have no knowledge of the drug names and the indications.
- Clinicians question the requirement for a phone approval being required in cases where they are prescribing “by the book” and approval is automatic. In these cases it is recommended that phone approvals cease to be required and the PBS implement a more cost effective auditing approach to ensure that clinicians have met the prescribing criteria and identify any outliers in prescribing.

Streamlined authority

- There are many cases where streamlined authority is not currently being systematically and equitably applied across drugs and treatment options in the public private and public sectors.

The Association would welcome the opportunity to meet with you and the members of your team to discuss the matters outlined in this letter, that fall under the control of the Pharmaceutical Benefits Advisory Committee. We would also like to accept your offer to assist the Association in setting up a face to face meeting with relevant contact/s in the Department of Human Services who manage the authority prescription approval process. We believe that many of these barriers and limitations result from the lack of clinician input to the development of the administrative processes and requirements that have been put in place, and look forward to working with the relevant individuals to address these issues. Improving these unwieldy processes would avoid the real negative impacts on patients that clinicians see regularly. With constructive input into these processes we could create a “win-win-win” scenario where patients, clinicians and the authorities all benefit from a reduction in unnecessary bureaucracy.

MOGA would be pleased to assist with any further information on the matters detailed herein or to answer any questions that the PBAC may have should this be required. We look forward to continuing to work with you and the members of the PBAC.

SUBMISSION TO THE SENATE INQUIRY INTO HEALTH SERVICES RED TAPE- 18 January 2018

Yours sincerely,

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