

Committee Secretariat
Red Tape Committee
Department of the Senate
PO Box 6100
CANBERRA ACT 2600



25 January 2018

Via email: redtape.sen@aph.gov.au

Dear Secretary

Select Committee on Red Tape Inquiry into the effect of red tape on health services

Medicines Australia welcomes, and thanks the committee, for the opportunity to make a submission to the above Inquiry.

Ultimately, the priority in any health system is the welfare of patients, and policies should be designed to support systems that enable provision of the best, timeliest and safest care possible. Medicines Australia and its members note that balanced regulation is critical to ensuring quality, safety and efficacy of such treatments.

At the outset, we acknowledge and are encouraged by steps already taken by the Australian Government to streamline processes and expedite access for some high priority medicines, including the Priority Review pathway consistent with the recommendations of the Medicines and Medical Devices Review (2015). We are hopeful that remaining reforms that will further accelerate appropriate access are endorsed by the Senate Committee on Community Affairs Legislation Committee Inquiry into the TG Bill (2017 Measures No.1), which includes a formal provisional approval pathway process. It will also be important to ensure that the TGA technology systems can support the revised regulatory processes needed to accelerate medicines access. We welcome any further consultation with Government to progress the reforms for the benefit of Australian health consumers. Government's commitment to improving access to innovative medicines is further reinforced through the Strategic Agreement signed in 2017 that will enable listing of medicines on the PBS to occur in a more timely and efficient manner, and will implement improvements to prescribing, dispensing systems and notifications that will create further efficiencies and improve health outcomes.

Clinical trials

Terms of Reference (2) of the Inquiry states; 'any specific areas of red tape that are particularly burdensome, complex, redundant or duplicated across jurisdictions'.

Medicines Australia proposes that one area where further action can and needs to be taken to ensure Australia can maintain international competitiveness and secure investment is in the field of clinical trials. These trials not only provide Australian patients early access to innovative therapies, they also offer employment and training

opportunities for highly skilled science, technology, engineering and mathematics (STEM) workers.

In 2016, approximately 1360 clinical trials were started in Australia, and the total direct expenditure for ongoing clinical trials has been estimated to be \$1.1 billion in 2015¹. An internal survey of Medicines Australia members recently found that in 2016 approximately 970 clinical trials were conducted by them, in over 4200 sites across Australia. The Australian Government has recognised that further support for the commercialisation of MedTech is a key area to stimulate economic growth in Australia through the establishment of MTPConnect.

Efficient quality assurance of clinical trials is critical to improving health outcomes and the overall productivity of the economy. However, differences in ethics approvals and research governance systems, even intra-state, are costing Australia and hampering its potential to attract even more clinical trials.

Ongoing challenges include:

- Slow and inefficient regulatory processes for approval for multi-centre clinical trials:
- Non-existent or inadequate patient referral networks that would enable faster patient recruitment and therefore trial completion; and
- High and unpredictable cost of conducting clinical research in Australia.

Medicines Australia would draw attention to its March 2017 submission to the Senate Select Committee into funding for Research into Cancers with Low Survival Rates. Part 1.1 of the submission outlines key recommendations to increase Australia's competitiveness and ability to attract more clinical trials².

Solutions to these challenges have previously been identified through the recommendations of the Clinical Trials Action Group³, and whilst we acknowledge progress is being made, we would support measures to further expedite their overdue implementation.

We ask this Committee to recognise the findings of the Senate Select Committee into Funding for Research into Cancers with Low Survival Rates which made the following recommendations in November 2017⁴:

Recommendation 6:

3.129 The committee recommends that Australian governments, as a priority, further streamline ethics and governance approval processes for clinical trials, particularly where those processes differ between states and territories, and public and private research institutions.

¹ MTPConnect, 2017, 'Clinical Trials in Australia: the economic profile and competitive position of the sector'.

² Medicines Australia 2017; Submission to the Senate Select Committee into Funding for Research into Cancers with Low Survival Rates.

³ Commonwealth of Australia, 2011, Clinically Competitive: Boosting the Business of Clinical trials in Australia.

⁴ Commonwealth of Australia, 2017, Senate Select Committee into Funding for Research into Cancers with Low Survival Rates. Report

3.130 Further, the committee acknowledges the work that the National Health and Medical Research Council (NHMRC) has done to reduce unnecessary regulatory barriers with respect to ethics processes, and while it recognises that some processes are beyond the scope of the NHMRC, the committee considers that the NHMRC could make further changes in order to eliminate those existing, significant regulatory delays.

3.131 Specifically, the committee considers that the NHMRC could develop a standard template and associated guidelines, including timeframes, for ethics and other governance approvals that could be adopted by every state and territory. This in turn could allow for the approval from one institution to lead to automatic approval at any other institution.

Recommendation 7:

3.132 The committee recommends that the NHMRC develops a standard template and associated guidelines, including timeframes, for ethics and other governance approvals for consideration and possible adoption by each state and territory.

We would certainly welcome further consultation to ensure such reforms are expediently made and note that our Research & Development Taskforce, which comprises representatives from across the clinical trials sector including clinical research institutes and organisations and the Medical Technology Association of Australia, would be happy to discuss such reforms with the Committee.

Payroll tax

The Terms of reference (5) of the inquiry state that ‘alternative institutional arrangements to reduce red tape, including providing subsidies or tax concessions to businesses to achieve outcomes currently achieved through regulation’.

The strength of the innovator medicines industry depends on the extraordinary talent of its people, and their skills and knowledge. Payroll tax has been identified as a burden for companies. The Australian Government as part of the tax reform measures should further commit to working with the States and Territories to reduce the rate of payroll tax for STEM graduates who are working in identified innovative industries such as pharmaceuticals. Such a reduction would provide a tangible incentive for companies, and will form part of the competitive localization package offered by States and Territories for business to invest in their state⁵.

Health Technology Assessment (HTA)

Medicines Australia agrees with the Australian Government that a well-performing HTA system will:

- *facilitate patient access to cost-effective health technologies that improve health outcomes;*
- *minimise the use of technologies that are ineffective or harmful;*
- *contribute to value for money investments in health technology in the context of limited health care resources;*

⁵ Medicines Australia 2017; Federal Budget Submission 2017/2018.

- *keep pace with evolving technologies, clinical practices and HTA methodologies;*
- *provide clear information on processes, rules and outcomes to stakeholders; and*
- *ensure the system is designed to achieve these outcomes in the most timely, effective, efficient and targeted way⁶.*

Health Technology Assessment is an area identified by a number of our members where there is opportunity to streamline processes and implement alternate pathways for submissions.

In 2017, Medicines Australia entered into a strategic agreement with the Commonwealth to work cooperatively to streamline the medicines listing process. Areas of focus include the availability of new medicines, cost recovery and PBS processes, to ensure best possible access for patients, provide confidence to industry and delivery savings to taxpayers. We look forward to working closely with the Australian Government on possible reforms and improvements in 2018.

Other areas for potential action

Medicines Australia members have previously identified the community pharmacy sector as subject to complex regulations that vary between jurisdictions. As such, Medicines Australia certainly welcomes the recommendation at Option 5-9 of the Review of Pharmacy Remuneration and Regulation Interim Report 2017 of harmonising pharmacy legislation. The recommendation states:

As early as practicable, the Australian Government, through the Australian Health Minister's Advisory Council, should seek to harmonise all state, territory and federal pharmacy regulations to simplify the monitoring of pharmacy regulation in Australia for the safety of the public. In the long term, a single pharmacy regulator could be considered. As an interim measure, state and territory registering bodies need to coordinate with the Australian Health Practitioner Regulation Agency to ensure that pharmacy regulations are being adequately monitored for best practice of pharmacy and the safety of the public⁷.

Medicines Australia suggests that the Government with the COAG may want to consider conducting a review of the various state-based regulations, to ensure they remain fit-for-purpose and we look forward to learning of next steps regarding the Interim Report.

Progress being made with regards to e-Prescribing should also be noted. Specifically, the Strategic Agreement between Medicines Australia and the Commonwealth of Australia includes the development of a national consumer-centric e-Prescribing system intending to improve real-time reporting, recording and monitoring of controlled drugs by means of the national Electronic Recording and Reporting of Controlled Drugs system⁸. Medicines Australia looks forward to

⁶ <http://www.health.gov.au/internet/hta/publishing.nsf/Content/about-1>

⁷ Commonwealth of Australia 2017. Review of Pharmacy Remuneration and Regulation Interim Report

⁸ Commonwealth of Australia and Medicines Australia Strategic Agreement 2017

participating in consultations on this and other improvements to medications prescribing, dispensing and monitoring systems to enhance medication safety.

Communication Between Regulators

At the Commonwealth level, the Therapeutic Goods Administration (TGA) is the principal regulator for innovator medicines. At the same time, the Australian Competition and Consumer Commission (ACCC) is responsible for administering Australian Consumer Law. Regulators need to co-ordinate with one another particularly where there is risk of jurisdictional overlap. We are aware that the ACCC has recently commenced consultation on claims regarding complementary medicines and country of origin statements. It is not clear to us that the two regulators are coordinating efforts in this area. We would not like to see a similar situation in relation to innovator medicines; potential inconsistent regulatory approaches must be avoided in order to reduce the risk of unnecessary red tape.

Key Performance Indicators (KPIs) at Commonwealth Level

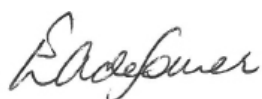
We note that at the national level, many regulators must report annually on the industries they regulate, using a national KPIs framework. The regulators must report into the Australian Department of Prime Minister & Cabinet. Although this is a recent initiative, the reporting requirements on the TGA are considerable and the KPIs are not particularly useful to industry when assessing such things as red tape and administrative complexity imposed by regulators, which in turn, at least for the TGA, are cost-recovered. Similarly, the TGA has made many positive inroads to reduce red tape but the KPIs Framework does not easily accommodate such feedback to be presented. We consider there would be merit in exploring more meaningful approaches to measure regulators' performance and commitments to reducing red tape.

Sunsetting

The sunseting of regulations is also an area that we think warrants further examination. Whilst the intention is that such an initiative reduce red tape, we consider that agencies should be adequately funded to periodically conduct and assess the relevance and appropriateness of regulations. Conducting a cost benefit analysis of the current default sunseting approach compared to regular and/or rolling reviews of regulations may be of merit.

We are always more than happy to discuss any aspect of this submission further with the Committee. I can be contacted on 02 6122 8525 or by email edesomer@medaus.com.au

Yours faithfully



Elizabeth de Somer
Director, Policy & Research

