



9 May 2019

Elizabeth de Somer
Chief Executive Officer
Medicines Australia

BY EMAIL: jsnashall@medaus.com.au

Dear Ms de Somer

Thank you for your letter on Medicines Australia's policy priorities for the upcoming federal election. We appreciate this opportunity to reiterate Labor's strong support for the innovative medicines sector.

Labor created the Pharmaceutical Benefits Scheme (PBS). More than 70 years later, we continue to fight for affordable access to medicines for all Australians – including to the life-saving drugs that your members develop and manufacture.

We are therefore pleased to respond positively to each of your five policy priorities.

PBS listing processes

As you know, Bill Shorten used his 2019 Budget Reply Speech to announce a major commitment on medicines – Labor's Affordable Medicines Guarantee.

Under this Guarantee, a Labor Government will list every medicine that is recommended by the independent Pharmaceutical Benefits Advisory Committee (PBAC) on the PBS.

While the Liberals make the same claim, Senate Estimates has revealed that at least 18 recommended medicines have been withdrawn before listing because pricing negotiations have broken down. This has denied Australians access to vital medicines for a range of conditions.

In contrast, a Labor Government will list every recommended medicine, and meet the Department of Health's official target on listing recommended medicines within six months of pricing agreement. Labor will continue to report at least annually on the achievement of this metric.

Labor will also pursue reforms to improve the efficiency, transparency and timeliness of PBS listings, as described in clause 10.3 of Medicines Australia's Strategic Agreement with the current Government.

National Medicines Policy review

The PBS, Life Saving Drugs Program and National Immunisation Program are underpinned by the National Medicines Policy. Its key objective is to ensure “timely access to the medicines that Australians need, at a cost individuals and the community can afford”.

Almost 20 years after the National Medicines Policy was agreed, its objectives remain sound – including its pillar of a sustainable medicines sector.

But Labor agrees with PBAC Chair Professor Andrew Wilson that the National Medicines Policy has been undermined by “piecemeal approaches.” For example, while reforms to streamline Therapeutic Goods Administration (TGA) processes are welcome, they may simply shift the existing ‘bottleneck’ from registration to subsidy.

Labor will act on the advice of Professor Wilson and others to review how the aims of the National Medicines Policy could be better met.

Labor’s review will consider the entire medicines pipeline, from research and development to the quality use of medicines by consumers. It will consider a range of developments that present opportunities but also challenges for the National Medicines Policy, including:

- An increasingly competitive global environment for innovation and clinical trials.
- Increasingly targeted medicines, such as for rare cancers and other rare diseases, that have limited data and/or high unit costs.
- The role of managed entry schemes and real world evidence in subsidising these medicines, and the responsibilities of governments and sponsors in such schemes.
- Other new therapies that aren’t traditional ‘medicines’ or ‘services’ and therefore fall between the cracks of PBS and Medicare.
- Any further changes to TGA, PBAC and other processes that could improve access to medicines while retaining a rigorous focus on clinical and cost effectiveness.
- Evidence that large numbers of Australians are struggling to afford medicines and, in many cases, not filling prescriptions.

Further to our discussions in recent months, Labor will also ask the review to consider whether a legislated Medicines Fund could contribute to affordable and timely listings.

Labor acknowledges that governments deliver the PBS in partnership with researchers, medicines companies, distributors and pharmacists. Labor will work with these groups and consumers to finalise the format of the review, and throughout its conduct.

The National Medicines Policy Review will provide recommendations for consideration and possible implementation in the first term of a Shorten Labor Government.

Strategic Agreement

Labor is committed to working in partnership with industry to deliver affordable and timely access to medicines to all Australians.

Labor understands the importance of special pricing arrangements (SPAs) in bringing medicines to Australia, and knows that your members are currently alarmed by the Liberals’ proposed reforms to

the supply chain in general, and SPAs in particular. A year after the Liberals booked significant changes in the 2018 Budget, it is clear that they still do not know how to implement their reforms, causing significant uncertainty for your members and other medicines stakeholders.

In the first instance, a Shorten Labor Government would ask the Treasury, Department of Finance and Department of Health to develop an accounting solution to these issues. Should an accounting solution not prove possible, Labor commits that any reforms would not have an adverse impact on your members' capacity to bring life-saving drugs to Australia, including through SPAs.

More broadly, Labor agrees that regular strategic agreements – such as the 2010 agreement between Medicines Australia and the former Labor Government – are a crucial tool in formalising this partnership.

Labor has no plans to make medicines policy changes. However, the National Medicines Policy Review, the SPA Reforms, as well as the 7th Community Pharmacy Agreement – on which Labor has committed to lead early and inclusive negotiations and to give Medicines Australia a seat at the table – may have implications for the medicines pipeline.

We therefore reiterate our view – expressed since 2017 and noted in your letter – that a Shorten Labor Government may seek to negotiate a strategic agreement with Medicines Australia. This openness in approach is in everyone's interest - particularly the medicines industry, if we are to jointly action recommendations or findings from the NMP Review and other policy concerns such as SPA reforms.

However, Labor understands the importance of stability and certainty for your members and will honour any new agreement – in contrast to the Liberals, who have continually undermined various aspects of your existing agreement.

Labor will also re-establish the Pharmaceutical Industry Working Group – an important forum for engagement with medicines companies that was inexplicably abolished by the Liberals.

Clinical trial harmonisation

Labor understands the vital role that clinical trials play in expanding access to life-saving medicines, and developing new therapies. Our most important policy document – the ALP National Platform – includes our commitment to “support measures to maintain and expand clinical trials and patient access to them.”

Labor has also made substantial funding commitments to clinical trials, including a \$26 million commitment to expand patient access and embed clinical trials in all parts of our health care system.

Labor agrees that better harmonisation between governments and other stakeholders would improve access to clinical trials and commits to take a proposal to the Council of Australian Government's Health Council in the first year of a Shorten Labor Government.

Research and development and intellectual property

Labor is proud of creating the Research and Development (R&D) Tax Incentive, the single largest investment the Commonwealth makes in supporting science, research and innovation in the Australian economy.

But the chaos and dysfunction of the Abbott-Turnbull-Morrison Government has diminished the effectiveness of the R&D Tax incentive. Even a Liberal-dominated Senate Inquiry rejected the Government's own proposals for reforming the incentive because they discriminated against the manufacturing industry.

That's why a Shorten Labor Government will reform the R&D Tax Incentive to help more firms to do quality research and development here in Australia and employ more Australians.

Labor will change the program objectives of the R&D Tax Incentive scheme so that improving Australian business collaboration with research institutions will be an explicit target.

Under Labor's reforms, firms that collaborate with researchers in universities and public research agencies to create new knowledge will be eligible for a 10 per cent premium.

These reforms will help achieve Labor's ambitious national target of devoting 3 per cent of GDP per year to research and development by 2030, a key priority of a Shorten Labor Government.

As well as reforming the R&D Tax Incentive, a Shorten Labor Government will undertake the first root and branch review of Australia's research sector in 30 years.

The Australian pharmaceutical system operates within a wider global system of pharmaceutical research, development and supply. Australia is a small market and a net importer of technology and medicines. Data exclusivity is an important issue and needs to be considered in a broader context.

As above, Labor has a commitment to re-establish the Pharmaceutical Industry Working Group, and we look forward to discussing this and other issues regarding research and development investment in Australia through this forum.

Yours sincerely

Australian Labor Campaign Headquarters
www.alp.org.au