

10 July 2015

Senator Zed Seselja
C/o Committee Secretary
Senate Standing Committee on Community Affairs
PO Box 6100
Parliament House
CANBERRA ACT 2600

Via email: community.affairs.sen@aph.gov.au

Dear Senator

Thank you for the opportunity to comment on the Senate Community Affairs Legislation Committee inquiry into the *Medical Research Future Fund Bill 2015* and the *Medical Research Future Fund (Consequential Amendments) Bill 2015*. Medicines Australia appreciates being able to highlight the need for continued and further investment in medical research in the innovative medicines industry.

Recommendations

Medicines Australia supports the passing of the *Medical Research Future Fund Bill 2015* and the *Medical Research Future Fund (Consequential Amendments) Bill 2015*. To ensure the greatest value from the MRFF, Medicines Australia also recommends the following:

- **Involvement** of relevant partners including industry to ensure alignment between the MRFF and the Medical Technologies and Pharmaceuticals Growth Centres, part of government's Industry Innovation and Competitiveness Agenda.
- **Consultation** on appropriate policies to improve Australia's competitiveness through innovation including R&D credits and clinical trial reforms.

Introduction

Medicines Australia represents the research-based innovative medicines industry in Australia. Today, over 50 pharmaceutical companies and around 400 locally-owned medical biotechnology firms, operate in Australia. Together, they employ approximately 40,000¹ highly-skilled Australians (with at least 14,000 jobs² directly within our member companies), invest more than a combined \$1 billion in manufacturing and clinical research and development³ and generate nearly \$2.9 billion in exports each year⁴. Our member companies supply up to 86% (by value) of the therapies available on the Pharmaceutical Benefits Scheme (PBS) – medicines and vaccines that help millions of Australians live healthier, longer, more productive lives.

¹ Comprises bio-medical research, biotechnology firms, originator and generic medicines companies and service related segments including wholesaling and distribution: Department of Innovation, Industry, Science and Research, Pharmaceutical Industry Fact Sheet, available at:

www.innovation.gov.au/Industry/Pharmaceuticals/Pages/AustralianPharmaceuticalsIndustryFactSheet.aspx

² IBIS World, Melbourne, 2014, Pharmaceutical Product Manufacturing in Australia: Market Research Report

³ Australian Bureau of Statistics 2012, 'Business Expenditure Report on R&D'

⁴ Australian Bureau of Statistics 2015, 'International Trade in Goods and Services': March 2015

Medicines Australia welcomes and supports the *Medical Research Future Fund Bill 2015* as a dedicated financial asset supporting medical research and innovation. Long-term policy setting and planning in our industry is crucial to attracting and fostering further research and development funding in Australia. Moreover, this may be viewed as a signal to global pharmaceutical companies with the expertise to complement the research and commercialisation of new medicines, that Australia is committed to regaining its reputation for innovation and investment in medical science. It should also attract local companies to commit to furthering operations in Australia.

Current Opportunities

As the Asia Pacific region is poised for growth, there are a number of economic and regulatory opportunities for the Australian pharmaceutical industry. Some of these opportunities may be further supported through increased investment in research and development, such as the MRFF.

The MRFF could be harnessed to improve Australia's economic future, encouraging greater collaborative links between the public research and the business sectors, including Australia's pharmaceutical industry. It is important that together we leverage Australia's local strengths, including the quality of our medical research and health system, to provide stronger competitive advantage for the nation and the health of Australians.

Medicines Australia members already work productively to partner with research institutes, universities and other relevant bodies such as the National Health and Medical Research Council and Therapeutic Innovation Australia, working better together at bringing research from the laboratory to the patient.

Objectives of the MRFF are likely to align well with the Government's Industry Innovation and Competitiveness Agenda. The Medical Technologies and Pharmaceuticals Industry Growth Centres aim to lift competitiveness and productivity by focusing on areas of competitive strength, transitioning Australia to smart, high value and export focused industries. Of the five priority growth sectors, the medicines industry figures in two: Advanced Manufacturing and Medical Technologies and Pharmaceuticals. Companies and research organisations across the Medical Technologies, Pharmaceutical and Biotechnology sectors are expected to, among other things, encourage collaboration and enhance the commercialisation of new products. Medicines Australia is willing to assist in ensuring the capabilities of both programmes can be harnessed, and will align for mutual benefit.

With supportive policy settings, the innovative pharmaceutical industry has the potential to be one of the key innovative industries for Australia's future. The next decade will provide enormous opportunities, with the Asia Pacific region set to drive huge demand for medicines as its middle class population is anticipated to double. Australia is uniquely placed to meet this demand, with a highly-skilled workforce and a long-standing reputation for manufacturing safe, high-quality medicines and vaccines. To harness this opportunity grants and funding through the MRFF Health Special Account can assist in translating research into new innovative pharmaceutical products that will change Australian lives.

Australia currently exports medicines to over 70 countries. The right policy settings could see Australia potentially double its share of the global pharmaceutical market (currently

approximately 1%⁵) over the next decade. Medicines Australia welcomes opportunities to work with Members of Parliament in any efforts that can help realise this economic opportunity for Australia.

Current Challenges

Despite this opportunity, there are several challenges facing the industry that are making it more difficult to achieve this aforementioned potential growth. In fact, the local industry has been in decline now for a number of years. Historically, medicines had been Australia's leading manufactured exports, but recently have fallen and are now ranked second⁶. In fact, Australian pharmaceutical exports plummeted by nearly a third from \$4.3 billion to \$2.9 billion between 2012 and 2014. As a result of this decline in exports, eight pharmaceutical manufacturing plants have either closed or been significantly downsized since 2007⁷. Increasing investment in R&D will limit the industry's apparent contraction and may in fact help reinvigorate the industry.

Since 2007, as many as 2,500 jobs have been lost across the Australian pharmaceutical industry. Reversing the sector's contraction will undoubtedly reduce pressure on jobs faced in the recent fiscal environment. R&D, intellectual property or direct foreign investment will all benefit and improve. In this context, the innovative medicines industry is sensitive to any further policy changes that would negatively alter the current business environment.

Australia faces stiff competition from other countries for investment funding for the research, development and often subsequent manufacturing of innovative medicines. Countries such as Singapore offer significant incentives to attract investment. Currently, Australia's share of global outward trade in pharmaceutical goods and services is less than 1%⁸. This is despite pharmaceutical manufacturers in Australia having a competitive advantage with our high-quality science, highly-skilled work force and access to facilities. Even though Australia has a reputation for manufacturing safe, high-quality medicines and vaccines, imports are significantly higher than exports. Growing manufacturing capacity would help Australia to maintain a healthy balance of trade in pharmaceutical goods and services in the future.

A positive development by government in recent years was the R&D Tax Incentive introduced by the *Tax Laws Amendment (Research and Development) Bill 2013*. Similar to other countries, Australia's R&D tax incentive encouraged further investment in R&D whilst also suppressing a company's effective tax rate. Although this incentive was a signal of support for increased investment, we have already seen reductions in the credit rate less than three years after it was first implemented. These changes have directly undermined Australia's reputation as a stable and predictable business environment and will impact our ability to attract R&D investment in the future.

The cost of development of a new prescription medicine that gains marketing approval is over \$US 2.5 billion⁹. This includes the costs of the pre-human and clinical phases of development. Consequently pharmaceutical companies require stability and certainty once medicines are on the market to enable further investment in new innovative products. In

⁵ Medicines Australia 2015 Facts Book 4.

⁶ Ibid.

⁷ Ibid.

⁸ World Trade Organisation, Geneva, 2013, 'International Trade Statistics, Merchandise Trade'.

⁹ Tufts Center for Study of Drug Development 2015. Cost of Developing a New Drug.

addition to this, it takes on average 12-15 years from preclinical trials to when the medicine is widely available to patients. Due to this long lead time, any material changes in policy will influence decisions on where to invest in R&D for new innovative medicines¹⁰. We want Australia to be the first choice investment destination.

MRFF, R&D and the Australian Innovative Medicines Industry

The MRFF disbursements are estimated to inject millions into research and development over the next four years and Medicines Australia expects long term flow on effects in terms of greater innovation. Disbursements from the MRFF will contribute to retaining highly skilled scientific research jobs in Australia, stimulating other sectors in the economy. Increased research activity will lead to more commercialisation opportunities. These commercialisation opportunities will, in turn, provide the greatest benefit from the MRFF investment, further business investment in Australia and access to new innovative medicines that will improve Australians' health.

Medicines Australia notes with interest the newly announced Government Review of research funding and policy (Tuesday 7 July 2015 [Media Release](#), The Hon Christopher Pyne MP). Action taken to improve the commercialisation capabilities of research and development in Australia is welcomed by the industry. Yet we note, strong efforts to improve R&D funding must be the first step. Local investment in R&D and high-tech manufacturing generate new intellectual property for Australia, enhance local infrastructure and production capacity, and create new jobs in advanced manufacturing and other highly-skilled fields in Australia. These key economic drivers have positive outcomes, increasing not only in innovation, productivity and economic activity.

Tax policy settings have a direct impact on the level of investment in research and development where these policies apply. The pharmaceutical industry is a critical component of Australia's innovative industries,¹¹ already undertaking more than a combined \$1 billion of manufacturing and clinical medical Research and Development (R&D) annually in Australia¹². This high level of investment has myriad important benefits for the country, including enhancing the physical health and welfare of Australians and helping to reduce health costs. It has been estimated that a dollar invested in Australian health research and development (R&D) will return an average health benefit of \$2.17¹³.

Local R&D has not only facilitated and enabled the development and commercialisation of important Australian discoveries, such as the human papillomavirus vaccine for cervical cancer, but also brought high quality medicines and vaccines to consumers around the world.

Clinical Trials

A competitive tax system and stable policy setting is also vital for Australia to attract more investment into clinical trials.

¹⁰ Medicines Australia 2015. Submission to The Treasury Re:Think Tax Discussion paper.

¹¹ Department of Industry, Canberra, 2014, Australian Industry Report

¹² Australian Bureau of Statistics 2012, 'Business Expenditure Report on R&D'

¹³ Access Economics 2008. Exceptional Returns: The Value of Investing in Health R&D in Australia II

There are more than 12,000 new medicines¹⁴ and vaccines in development globally; more than 1,000 by the five largest Medicines Australia members. However, there has been a sharp drop in the number of new clinical trials launched in Australia. In 2012, there were 759 clinical trials launched in Australia; in 2013 that fell to 681 new trials¹⁵. There has been a 20% overall drop in trial numbers since the peak in 2007¹⁶.

The decline in clinical trial investment means Australian patients are not getting the earliest possible access to new and innovative medicines. Delays in gaining ethics approval and recruiting patients are also contributing to a decline in Australia's competitiveness, which means these clinical trials are moved overseas instead and Australian patients miss out. With fewer clinical trials, high-skilled and high-paying Australian jobs are at risk. Policy decisions, such as the allocation of disbursements from the MRFF to medicines research, would enhance the attractiveness of clinical trials investment, and would have the two-fold benefit of increasing patient health outcomes as well as stimulating the economy through more highly skilled jobs remaining in Australia.

Conclusion

Medicines Australia supports further measures that will increase opportunities for increased research into pharmaceutical products. The MRFF Bills if passed will provide a unique chance to reinvigorate investment to conduct R&D and to manufacture medicines in Australia and continue supporting the Australian innovative medicines industry as a dynamic, vital part of the Australian economy and society.

Thank you for your consideration of our submission. We will be happy to answer any further questions or provide more detail at any inquiry hearings that may occur in relation to this initiative.

Yours faithfully

Tim James
CEO
Medicines Australia

¹⁴ Citeline Pharma R&D Annual Review 2015 https://citeline.com/wp-content/uploads/2015/02/CITIF_RD_AnnualReview_031715.pdf

¹⁵ Therapeutic Goods Administration Half Yearly Performance Reports

¹⁶ Medicines Australia 2015 Facts Book 4.