

## *Policy Cures submission to the McKeon Review*

*March 2012*

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Policy Cures welcomes the opportunity to make a submission to the independent review of health and medical research in Australia, and so provide input to the 10-year strategic health and medical research plan for the nation.

Policy Cures is an independent not-for-profit group based in Sydney and London, providing research, information, decision-making tools and strategic analysis to those involved in global health research. This submission focuses on medical research for diseases of the developing world, such as development of new drugs, vaccines and diagnostics for diseases like AIDS, tuberculosis, malaria and sleeping sickness (often referred to as ‘neglected diseases’).

Policy Cures stakes its reputation on providing neutral, balanced analysis built on in-depth understanding of, and relations with, organizations from all sectors of the health research and development (R&D) spectrum, including government, multilateral, philanthropic, private sector and civil society. We have conducted projects for high-profile organisations in Australia and overseas, including the Bill & Melinda Gates Foundation, Wellcome Trust, World Bank, World Health Organisation and AusAID.

Our submission focuses on Terms of Reference items: 2, 3, 4, 5, 8, 12 and 13

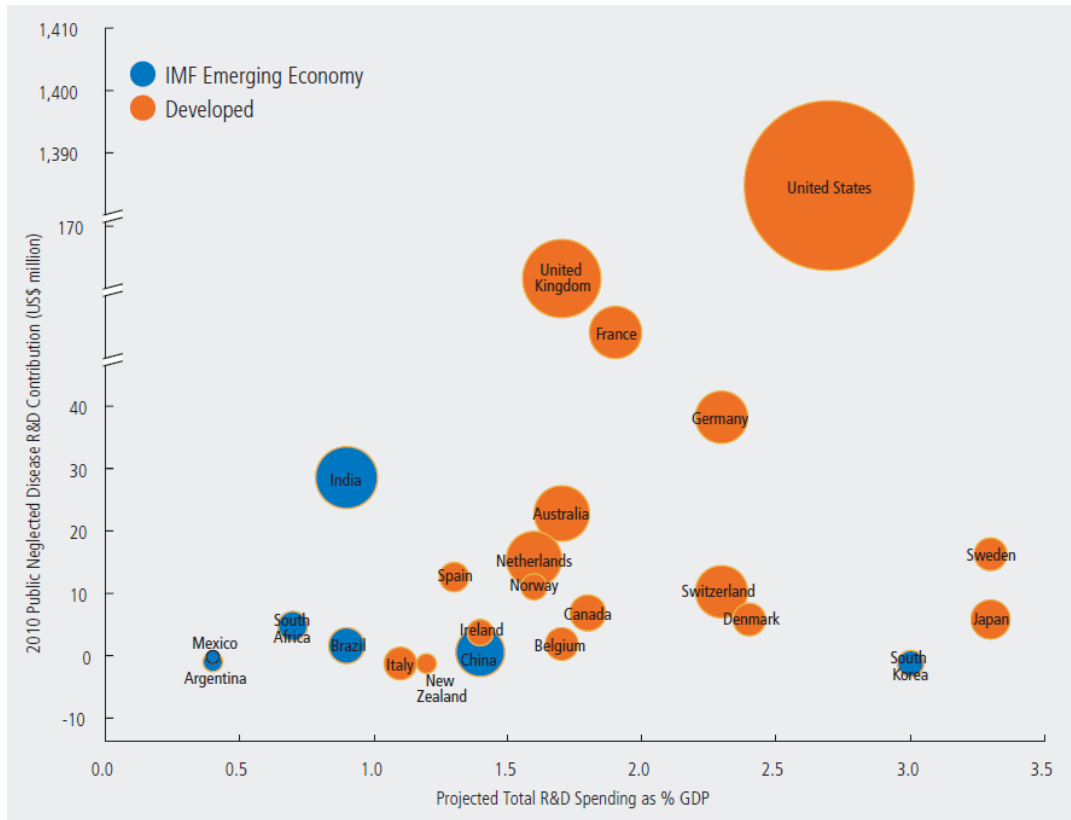
- **How might health and medical research be best managed and funded in Australia? (Terms of Reference 2, 3 and 7)**

2. Current expenditure on, and support for, health and medical research in Australia by governments at all levels, industry, non-government organisations and philanthropy; including relevant comparisons internationally.

Despite growing expenditure by the NHMRC, Australia’s OECD ranking on health and medical research funding as a percentage of Gross Domestic Product (GDP) is declining. Australian spending is being surpassed by that from emerging economies, and has gained no ground on the US or UK, despite our enviable position as one of the only advanced economies to avoid a recession during the global financial crisis.<sup>i</sup>

Looking specifically at this country’s investment in research and development (R&D) for the developing world, the picture is even grimmer. Despite being one of the world’s wealthiest countries, the Australian Government contributes only around 1% of global public funding for R&D for neglected diseases; and Australian industry and philanthropic organisations essentially provide no funding.<sup>ii</sup>

Figure 1. Neglected Disease R&D Activity Relative to Overall R&D Activity



Source: BVGH (2012) The Product Developer Landscape<sup>iii</sup>

Plotted here are country contributions to neglected disease R&D (2010 G-FINDER data; Y-Axis), overall country participation in life sciences R&D as a proportion of GDP (R&D Magazine data; X-Axis), and number of neglected disease product developers per country represented by the size of the circles.

Corrected for GDP, the Australian government not only spends far less on neglected disease R&D than prominent funders like the US and UK, but also less than relative minnows like Luxembourg, Ireland and South Africa, as well as Switzerland and the Scandinavian countries.<sup>iv</sup>

This is partly due to the low priority given to global health by the major medical research agencies – neglected disease research constitutes less than a twentieth of the NHMRC’s research expenditure – but the true problem is a whole-of-government one. In particular, unlike most donor countries, Australia’s aid agency, AusAID, currently directs no funding at all to R&D of new products for neglected diseases. In contrast, the aid agencies of both the US (USAID) and UK (DFID) recognise this as an important pillar of development assistance, with USAID contributing more than triple the total investment of the Australian government (including NHRMC and DoD funding) and DFID four times as much.

Accordingly, Australia should significantly increase its overall investment in neglected disease R&D. An opportunity to do so would be for AusAID to double its health research spending, in line with the doubling of Australia’s aid budget to 0.5% of GNI by 2015-16, with the additional funds used to initiate a new budget line for R&D for neglected diseases. Doubling Australia’s contribution to neglected disease R&D would still leave us contributing only a fraction of the global total, but (*ceteris paribus*) would at least bring us level with Sweden – in terms of funding as a proportion of GDP – and put us within the top handful of countries in the world by this measure.

Individually, however, neither Australia’s aid program nor the various other government agencies in the field have the capacity or remit to manage investment across the spectrum of global health

research. Nor can one agency alone coordinate the transition from scientific discovery, to product development, to delivering health interventions to patients. This means that an improved mechanism for whole-of-government coordination is required, as discussed under Item 3.

**Recommendation 1:** Australia should significantly increase its overall investment in global health R&D, in line with the commitment to double ODA to 0.5% of GNI by 2015-16.

3. Opportunities to improve coordination and leverage additional national and international support for Australian health and medical research through private sector support and philanthropy, and opportunities for more efficient use, administration and monitoring of investments and the health and economic returns; including relevant comparisons internationally.

Improving coordination. To support this process, we recommend establishing an inter-agency global health working group. This group would collaboratively set Australia's global health priorities, identify funding and functional/skill gaps and allocate responsibilities between agencies based on their respective strengths and capacities. We support the findings of the recent DIISR (now DIIS RTE) 'Focusing Australia's Publicly Funded Research Review' – accepted by the Federal Government – which recommended formation of a multi-agency Australian Research Committee.

One of the key roles of the proposed working group would be to develop a coordinated and coherent research agenda, taking into consideration (and capitalising on the opportunities presented by) the recently completed reviews into innovation and aid.<sup>v vi</sup> In addition, the working group would provide a mechanism for engaging with the global health research community, both in Australia and overseas. This would likely be best achieved by engaging with peak research bodies – both in the consultation phase and beyond – and we note here the opportunity presented by the newly-formed Australian Global Health Researchers Alliance (GHRA).

Internationally there are a range of approaches to coordination. As an example of streamlined/integrative administration a national level, we note the **Research Council of Norway (Forskingsradet)**. The Council "reports to the science minister, but some 30% to 50% of its budget comes from other ministries, for which it manages and administers programs. The other ministries must direct their strategic research spending through the Forskningsradet and it reports back to those ministers."<sup>vii</sup> A more expansive approach to collaboration is the **US National Cancer Institute's Center for Global Health**, which brings together different US government agencies, foreign governments, NGOs, and pharmaceutical and biotechnology companies around a specific disease area, cancer, not dissimilar to the neglected disease area.

Leveraging additional funding. Our analysis shows that Australian global health research brings significant international investment into Australia. The global health R&D programs of over 30 Australian universities, biotechnology companies and other research groups now receive funding from overseas governments, philanthropic organisations and Product Development Partnerships (PDPs), often accounting for a significant proportion of their global health research budget.<sup>viii</sup>

Internationally, new government commitments to global health R&D have leveraged millions of dollars in funding from the philanthropic and private sectors; for example, the dollar matching commitments between the Gates Foundation and the UK and German governments, as well as the recent 'London Declaration', which secured matching contributions from 13 pharmaceutical companies, governments of the US, UK and UAE, the Gates Foundation and the World Bank.

By increasing focus and funding for global health, a coordinated Australian government research agenda will deliver opportunities to leverage even more national and international funding, and to

improve the efficiency of that investment.

**Recommendation 2:** Australia should establish an inter-agency global health working group, responsible for developing a coordinated, coherent global health research agenda that capitalises on the strengths of the relevant agencies. International linkages could be considered.

• **What are the health and medical research strategic directions and priorities and how might we meet them? (Terms of Reference 5, 12 and 13)**

5. Likely future developments in health and medical research, both in Australia and internationally.

Since 2000, there has been greatly increased activity in global health research and development. Government, philanthropic and industry funding for global health R&D was over US\$3 billion in 2010, with industry investments increasing by 35% in that year.<sup>ix</sup>

As a result, creation of new drugs for neglected diseases has doubled in the past decade, from 13 drugs in 25 years (1975-1999)<sup>x</sup> to 12 drugs in half that time (2000-2010). The current pipeline has over 360 products in development (including drugs, vaccines, diagnostics, microbicides and contraceptive technologies),<sup>xi</sup> some of which will become the successful new products of the next decade. Many involve innovative new technologies such as low-cost injectables and vaccine temperature sensors designed specifically to match the needs of low-income countries like India, China, Indonesia and developing countries in Africa.

But Australia has largely been left out of this surge of innovation, which has been led by UK, European and US governments and organisations.

We suspect that 2012 is one of the few chances for Australia to join this innovative push. Global health R&D is, for the first time, being simultaneously considered by all relevant Australian agencies, including this review and the AusAID and DIISRTE reviews on Aid Effectiveness and National Research Priorities respectively; and the financial climate is still sufficiently positive to allow consideration of dedicating some of Australia's wealth of knowledge and funds to helping those in the developing world.

12. The degree of alignment between Australia's health and medical research activities and the determinants of good health, the nation's burden of disease profile and national health priorities, in particular "closing the gap" between indigenous and non-indigenous Australians.

An increase of priority and funding to global health research and development can simultaneously deliver much needed health solutions for Australia's indigenous people. Although it is uncomfortable to admit, Australia's indigenous people currently suffer from a range of neglected diseases normally seen only in the developing world, in particular rheumatic fever, trachoma and leprosy. The Australian Government currently provides no funding for trachoma or leprosy R&D, and its funding for a badly needed rheumatic fever vaccine is less than US\$1 million per annum.<sup>xii</sup>

13. Opportunities for Australia's health and medical research activities to assist in combating some of the major barriers to improved health globally, especially in the developing world.

Australian health and medical researchers are currently developing innovative solutions to improving health outcomes for those in the developing world (but are not getting sufficient Government support to translate this into new products - see our comments below). For example:

- The Murdoch Children's Research Institute in Melbourne (MCRI) is developing an effective,

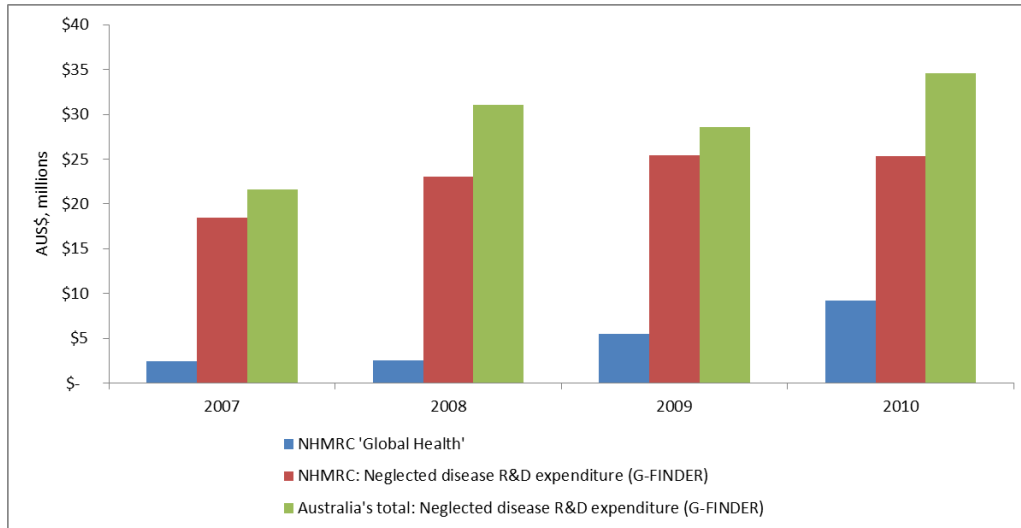
low cost rotavirus vaccine aimed at diarrhoea, now the second biggest killer of children under five years in the developing world. The translation work is being funded by PATH, a US-based PDP

- The Walter and Eliza Hall Institute (WEHI) is developing new malaria vaccines. This work is being funded by the Bill & Melinda Gates Foundation and the Malaria Vaccine Initiative, also a US-based PDP
- The Burnet Institute is developing a simple low-cost test to diagnose TB in developing countries<sup>xiii</sup>. This work is funded by the Gates Foundation
- Only a handful of Australian biotechs are active in global health due to lack of funding and national awareness: most of these are also funded by offshore PDPs due to lack of local small business funding support for global health R&D

We recommend:

- a) Making global health research a priority area within the 10-year strategic health and medical research plan for the nation, and funding it accordingly:
  - a. Commit to a new formal funding stream for applied global health R&D from **AusAID**, driven by AusAID’s medical research strategy for developing country health (now under discussion) (see Recommendation 1)
  - b. Increase the proportion of funding **NHMRC** allocates to global health
  - c. **DIISRTE** and **ARC** to identify programs (e.g. CRC, Commercialisation Australia and International Science Linkages Program) that could be adapted to incorporate a formal global health R&D stream. We note that the DIISRTE review specifically noted the need for increased international collaborations on R&D and highlighted the need to develop cures for diseases *that affect Australia and its neighbours*. (See Policy Cures’ submission on National Research Priorities)
- b) Developing a transparent process to identify global health research priorities, drawing on the skills, knowledge and expertise within Australia and Australia’s own priorities and encompassing the full spectrum of health and medical R&D (basic research, product development, operational research etc)
- c) Establishing an accepted definition of global health across the relevant agencies. The current NMHRC definition does not adequately capture research directed to this end. For example, data assessed and collated under G-FINDER, our annual report on funding for neglected disease R&D, found NHMRC’s investments for the years 2007-2010 were two to nine times higher than the research investments captured under NHMRC’S ‘Global Health Strategic Initiative’.<sup>xiv</sup> (see Figure 2)

**Figure 2. Australian expenditure on global health 2007-10**



**Recommendation 3:** Global health research should be identified as a priority area within the 10-year strategic health and medical research plan for the nation, and funded accordingly.

• **How can we optimise translation of health and medical research into better health and wellbeing? (Terms of Reference 4, 8, 9, 10 and 11)**

4. The relationship between business and the research sector, including opportunities to improve Australia's capacity to capitalise on its investment in health and medical research through commercialisation and strategies for realising returns on Commonwealth investments in health and medical research where gains result from commercialisation.

The reason there is little translation in the global health R&D field in Australia is surprisingly simple: the Australian Government preferentially funds non-applied R&D for global health. Data shows that:

- 84% of funding for applied R&D done by Australian researchers comes from overseas governments, philanthropists and PDPs
- Australian Government funding for applied global health R&D in 2010 was less than US\$10m per year across all 127 neglected disease research areas<sup>xv</sup>
- The Australian Government has by far the highest ratio of basic to applied research funding in the OECD, with over 60% of its neglected disease R&D funding going to basic research. Using malaria R&D as an example, the EC gives 18% of its malaria funding to basic research, the US gives 38% and Australia gives 80% - this is particularly remarkable given that badly-needed new malaria vaccines, drugs and diagnostics are now being developed and are in need of funding for their clinical development and commercialisation

We recommend:

- a) Creating dedicated applied R&D funding streams to follow-on from basic research funding (See Recommendation 1 for possible complementary funding streams from AusAID, DIISRTE)
- b) A greater policy focus on translational research, including by the proposed inter-agency working group (see Recommendation 2)
- c) Linking Australian researchers and companies to the international global health research community, including to PDPs whose specifically fund academics and companies to develop and 'commercialise' their research (in the field of neglected diseases, return on investment is generally measured in health not financial returns)
- d) The Australian Government could match overseas investments being used to fund promising Australian research beyond the basic research stage, leveraging the other investors' skills in

evaluating global health research projects (e.g. the Gates Foundation, PDPs)

**Recommendation 4:** A greater policy and financial focus on translational R&D, including creation of dedicated funding streams for applied global health R&D.

8. Opportunities to improve national and international collaboration between education, research, clinical and other public health related sectors to support the rapid translation of research outcomes into improved health policies and practices. This will include relevant international comparisons.

Australia could increase its focus on translational research by adapting/adopting best practice examples from overseas. These range from collaborative measures to more centralised approaches, for example, the US National Institutes of Health have established a technical office within the national research agency - the **US National Institutes of Health Office of Technology Transfer (NIH/OTT)** - tasked with commercialising scientific breakthroughs.

<sup>i</sup> Research Australia, *Shaping up : Trends and Statistics in Funding Health and Medical Research* (Melbourne: Research Australia, 2011).

<sup>ii</sup> Mary Moran et al., *Neglected Disease Research and Development: Is Innovation Under Threat?*, Global Funding of Innovation for Neglected Diseases (G-FINDER) Survey (Policy Cures, 2011), -.

<sup>iii</sup> Elizabeth Ponder and Melinda Moree, *Developing New Drugs & Vaccines for Neglected Diseases of the Poor - The Product Developer Landscape* (BIO Ventures for Global Health, 2012).

<sup>iv</sup> Mary Moran et al., *G-FINDER 2011*.

<sup>v</sup> DIISR, *Focusing Australia's Publicly Funded Research Review: Maximising the Innovation Dividend. Review Key Findings and Future Directions* (Commonwealth of Australia, October 2011).

<sup>vi</sup> Sandy Holloway et al., *Independent Review of Aid Effectiveness* (Canberra: Commonwealth of Australia, 2011).

<sup>vii</sup> DIISR, *Focusing Australia's Publicly Funded Research Review: Maximising the Innovation Dividend. Appendix D - Targeted Consultation Summary*.

<sup>viii</sup> Unpublished G-FINDER data

<sup>ix</sup> Mary Moran et al., *Neglected Disease Research and Development: Is Innovation Under Threat?*, G-FINDER Report (Policy Cures, December 2011).

<sup>x</sup> Mary Moran et al., *The New Landscape of Neglected Disease Drug Development* (The London School of Economics; Wellcome Trust, 2005).

<sup>xi</sup> Own analysis

<sup>xii</sup> G-FINDER unpublished data

<sup>xiii</sup> "Feature: A World Without Malaria," *Australian Life Scientist*, March 30, 2012, [http://www.lifescientist.com.au/article/352984/feature\\_world\\_without\\_malaria/](http://www.lifescientist.com.au/article/352984/feature_world_without_malaria/).

<sup>xiii</sup> Burnet Institute, "Novel Reagents for the Serological Diagnosis of Tuberculosis", 2012, [http://www.burnet.edu.au/projects/116\\_novel\\_reagents\\_for\\_the\\_serological\\_diagnosis\\_of\\_tuberculosis](http://www.burnet.edu.au/projects/116_novel_reagents_for_the_serological_diagnosis_of_tuberculosis).

<sup>xiv</sup> "National Health and Medical Research Council (NHMRC) Strategic Plan Initiatives and Special Initiatives for 2012." (NHMRC, 2012).

<sup>xv</sup> Figures are from G-FINDER unpublished data (see <http://www.policycures.org/publications.html>)