Australian Medical Research and Innovation Two Year Priorities

Title: Population Health Research Network Response to Medical Research Future Fund consultation for the development of the Australian Medical Research and Innovation Strategy and related Priorities

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1. **What is the gap in Australia's health system to be addressed by this priority?**

Current methods of post-market surveillance of pharmaceuticals in Australia are not sufficiently rigorous and result in unnecessary expenditure and sub-optimal use of medicines.

2. **How does your area of priority address either an existing or a new health or health system challenge?**

Australia has the skills and data resources to be a world leader in the safe and effective use of medicines, an area critical for a high quality health system, but has yet to harness these resources to achieve this potential.

3. **Comment on which aims and objectives your priority is likely to meet.**

A program of systematic post-market surveillance of pharmaceuticals in Australia using linked existing data collections would meet most of the aims and objectives of the Australian Health and Medical Research and Innovation Strategy including:

- Preventions and cures of tomorrow
- Economic benefits
- Sustainable, high-quality, cost-effective health care
- Leveraging and enhancing collaboration and integration
- A translation pathway that maximises opportunities for success
- Healthcare policy and delivery have a strong evidence base
- A research engaged workforce
- Contemporary infrastructure that meets research needs

4. **Mandatory considerations – which of the mandatory considerations set out in the *Medical Research Future Fund Act (2015)* does your priority proposal address?**

☐ Burden of disease on the Australian Community
☒ How to deliver practical benefits from medical research and medical innovation to as many Australians as possible
☒ How to ensure that financial assistance provides that greatest value for all Australians

☒ How to ensure that disbursements complement and enhance other assistance provided to the sector

5. Outline of priority proposal:

Prior to registration and inclusion in the Pharmaceutical Benefits Scheme (PBS), medicines have only been administered to a relatively small number of carefully selected patients. Post-market surveillance of medicines is an essential component in translating new medicines from experimental to successful treatments. It is vital to ensure the safety of medicines outside the carefully managed clinical trial environment. Australia's therapeutic vigilance system relies heavily on adverse event reporting by health professionals and health consumers. This can significantly underestimate adverse events, particularly rare events and long term effects.

Linkage of routinely collected/administrative data such as perinatal, hospital, emergency department, cancer registry and death data to the Pharmaceutical Benefits Scheme data can be used to systematically monitor and evaluate medicine safety and use. The benefits of using this approach to post-market surveillance are:

- Inclusion of the whole population
- Ability to detect rare adverse events
- Ability to detect effects of long term use of medicines
- Evaluation of effects of off-label use of medicines
- Evaluation of exposure to potentially inappropriate medications
- Identification of sub-groups for which medicines are either effective or ineffective.

This approach to post-market surveillance will provide a comprehensive understanding of the risk profiles of medicines, the groups in which they are effective and the groups in which they are not effective or harmful. It will also enable a better understanding of the cost effectiveness of medicines.

Australia now has the basic infrastructure in place, through the PHRN, to enable linked data to be used for national post-market surveillance of medicines and pharmacoepidemiological research. To achieve all the benefits described above routine linkage of state and territory health data collections to the Pharmaceutical Benefits Scheme data and the National Death Index is required. The PHRN is currently funding the establishment of this infrastructure and more work will be required to improve the timeliness of access to linked data for post-market surveillance.

6. What measures of success do you propose and what will be the impact on health care consumers?

- On-going enduring linkage of PBS data to National Death Index and Hospital Admitted Patient Data.
- Efficient processes in place to enable linked PBS, National Death Index and Hospital Admitted Patient data to be available for approved research in reasonable timeframes e.g. 3-6 months from initial application.
- Completed analysis on the safety, cost and use of medicines in Australia and related peer-reviewed publications.

The ultimate beneficiaries will be Australian health consumers who will receive safer and more effective medicines.

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7. Please outline any linkages your proposal has with stakeholders, policy agendas and other health and medical research funding agencies.

Stakeholders
Pharmaceutical industry
NCRIS health-related capabilities
State, territory and Commonwealth Health departments
The health system
Health and medical researchers
Consumers
National Health and Medical Research Council

Relevant policies
National Science and Research Priorities
National Innovation and Science Agenda