2022-23 Pre-Budget Submission
28 January 2022

No treatment left on the shelf; no Australian left behind.
Medicines and vaccines enable Australians to live their best, productive lives.

Sanofi recommends health budget measures that:
- ***Capture the full societal and economic benefit of investment in medicines and vaccines***
- ***Enable every Australian access to the best medicines and vaccines***
- ***Support investment in clinical trials***

The last two years living through a global pandemic has demonstrated the importance of good health and shown how Australians want to remain healthy and protect their livelihoods.

Investment in the medicines and vaccines industry will enable Australians to gain the full social and economic benefits through access to newly invented and world leading medicines and vaccines, as well as stimulating investment in research and development (R&D).

Sanofi is a global biopharmaceutical company characterised by a diverse portfolio of medicines and vaccines, including:

- 63 medicines funded on the Pharmaceutical Benefits Scheme (PBS);
- Seven vaccines funded on the National Immunisation Program (NIP);
- Two therapies funded via the National Blood Authority (NBA); and
- Five medicines funded on the Life Saving Drugs Program (LSDP).

In addition, Sanofi has a large pipeline of new therapies, which are underpinned by an enduring commitment to clinical research. Annually, Sanofi invests more than $20 million in R&D in Australia. In 2021, Sanofi invested $8.8 million in Australia for research dedicated to COVID-19. This included clinical trials, medical education, and research grants. The more medicines and vaccines made available to patients, the more investment we can make into discovering the next generation of therapies.

Clinical trials not only offer Australians early access to promising new treatments and potential cures they also have flow-on economic benefits to the broader healthcare system, and Australian economy. Clinical trial reform to streamline approval processes is urgently needed to ensure Australia remains an attractive location for clinical trials, which in turn will strengthen our healthcare system, and deliver benefits to the national economy.

RECOMMENDATIONS	RATIONALE
1. Measure the economic impact of medicine and vaccine investment: The Australian Government commission Department of Treasury to conduct economic modelling to investigate the long-term fiscal benefit of medicines listed on the Pharmaceutical Benefits Scheme (PBS) or National Immunisation Program (NIP) either since 2000, when the National Medicines Policy was launched, or a	Fully recognising the economic benefit of investment in medicines and vaccines will assist in future decisions on expenditure and could assist in the current Health Technology Assessment Review being conducted by the Department of Health.

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select list of key and essential medicines and vaccines.	
2. Resource the HTA Review: The Australian Government invest in Department of Health resourcing to ensure it is sufficiently equipped to collaborate with the innovative medicines industry to successfully implement all the terms of the Strategic Agreement 2022-2027 between Medicines Australia and the Commonwealth, including the Health Technology Assessment (HTA) Review.	Providing additional resources to support the substantial work involved in these historic reforms will enable the Department to continue their current responsibilities managing Australia's complex reimbursement systems
3. Establish a Provisional Medicines Fund: The Australian Government commit to funding a Provisional Medicines Fund, to align PBS reimbursement with provisional TGA registration, to offer early and interim access to priority medicines, for a limited number of patients. The estimated cost of the Provisional Access Medicines Fund would be $250 to $400 million per year (before rebates).	Early, interim access will enable the collection of more mature evidence from clinical trials and/or real-world data from Australian experience and allow patients access to potentially life extending or lifesaving treatments.
4. Simplify clinical trial approvals: The Australian Government, together with State and Territory Governments, reform clinical trial processes in line with the proposed 'National One Stop Shop' and thereby: 1. Reduce the regulatory inefficiencies across jurisdictions in the current system and save costs; 2. Improve patient recruitment into clinical trials and strengthen Australia's international competitiveness, delivering downstream economic benefits; and 3. Increase high-wage employment opportunities for Australians wanting a domestic career in R&D.	Red tape reduction and removal of procedures that result in delays for patients receiving access to medicines via clinical trials, not only benefits patients and their families, but also encourages further economic investment in research.