# GUARD Collaborative Australia welcomes tabling of the parliamentary report and recommendations regarding approval processes for new drugs and novel medical technologies

GUARD Collaborative Australia (Genetic Support Network of Victoria, Genetic Alliance Australia and Syndromes Without A Name (SWAN) Australia) welcomes the House of Representatives Health, Aged Care and Sport Committee Inquiry report into Approval Processes for New Drugs and Novel Medical Technologies in Australia, tabled in Parliament on Thursday 25th November.

The genetic, undiagnosed and rare disease community in Australia were actively involved through submissions and consultations. Our community are the experts in their health journey and expect to work with health professionals and Government to equitably access the right treatments at the right time to improve quality of life. We would like to thank all that contributed from all sectors. This report recommends increasing engagement and involvement with appropriate supports which is most welcome.

This social contract between people living with genetic, undiagnosed and rare disease, Government, health and social services demands that we equitably work together to merge the dynamic data, technology and scientific environment with systems and processes that allow innovation to become affordable, accessible and equitable.

We are very encouraged by the 31 recommendations in *The New Frontier - Delivering better health for all Australians* report. We look forward to a collaborative process to contribute to an implementation plan that includes broad inclusion and comprehensive consultation. Our community stands ready to contribute to the development of the detail for smooth implementation and the translation of these recommendations into tangible difference that will positively influence lives.

We welcome the following key recommendations from the House of Representatives Standing Committee on Health, Aged Care and Sport:

- A new HTA pathway be developed for cell and gene therapy in Australia
- The Department of Health expand its understanding and expertise of rare diseases with a focus on precision medicine and cell and gene therapies.
- The establishment of a 'Centre for Precision Medicine and Rare Diseases' within the Department of Health
- For the Australian Government should establish a National Genomics Testing Program to provide equitable access to genomics testing nationwide, including provision for genomics counselling for all patients.
- For the Department of Health to give the highest possible priority to strengthening the role patient evidence plays in its HTA decisions, particularly in relation to rare diseases.

- To re-establish the Australian National Congenital Anomalies Register (NCAR) and should consider how this register could be adapted to capture appropriate data for rare disease.
- The development of robust pathways that provide equity and access to treatments and therapies that don't fit neatly into the current system such as rare cancers, antimicrobials, orphan drugs, and upcoming precision medicines.
- To streamline a regulatory pathway to safely allow the use of cutting-edge, life-saving therapies in children sooner.
- For orphan drug designation to be automatically linked to the priority review pathway, to support faster access to medicines for rare disease patients so as to reduce the administrative burden on the TGA.
- For annual reporting on HTA processing times to be established for transparency and to benchmark these processes to international peers.
- A new approach that allows earlier and faster consideration to the Life Savings Drugs Program (LSDP)
- A more sustainable framework for rare disease funding and risk-sharing arrangements between manufacturers and the Australian Government.
- For the Australian Government to urgently expand and complete the standardisation of the national newborn screening framework so that every baby born in any state or territory of Australia receives the same newborn screening test with a review every two years.

This is a report of potential, there are many recommendations which will require ongoing appetite for implementation from all stakeholders. It must result in better access to diagnostics, treatment and therapies and quickly. We cannot delay commencement of a collaborative implementation process. Our systems are not fit-for purpose today, let alone tomorrow.

A healthy Australian economy depends on a healthy Australian population, we all want that. It's not going to happen from a progressive report, we need action. This is an exciting time of opportunity and innovation. It's time to create health systems and processes that are built on equitable access and to deliver the healthcare that all Australian's deserve in a cultural environment in which we all wish to live.

The report is available at
https://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/Newdrugs/Report