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Inquiry into approval processes for new drugs and novel medical technologies in Australia

The George Institute for Global Health is pleased to make a submission to the House of Representatives Standing Committee on Health, Aged Care and Sport in relation to their Inquiry into approval processes for new drugs and novel medical technologies in Australia.

The George Institute is a leading independent global medical research institute, established and headquartered in Sydney, with major centres in China, India and the United Kingdom, and an international network of experts and collaborators.

Our mission is to improve the health of millions of people worldwide, particularly those living in under-served or low resource settings, by challenging the status quo and using innovative approaches to prevent and treat non-communicable diseases (NCDs) and injury.

In October 2019, The George Institute established Genovate, a social entrepreneurship and innovation program. It is dedicated to creating new healthcare solutions that address unmet health needs in underserved populations. Genovate works with our researchers and partners to fast track product development and guide innovation teams toward commercialisation and market success, so we can improve the lives of millions of people.

George Health

George Health was established to support The George Institute to commercialise its research. It provides fast, affordable, simple and scalable new treatments for patients, and exciting investment opportunities that combine strong commercial returns with real social impact. George Health has four established businesses that are poised for significant growth, and integrated in a way that enables innovative health products and services to be taken all the way from concept to market, in a relatively short time frame.

The George Health businesses are:

- **George Clinical:** Science, service, solutions. A leading Contract Research Organisation (CRO) in Asia-Pacific with global capabilities.
- **George Medicines:** Innovative, affordable treatments for the leading causes of death globally.
- **George Health Technologies:** Affordable, personalised digital health care for all.
- **Ellen Medical Devices:** Creator of the world's first affordable dialysis system.

In March 2020, George Health received AU$20 million to develop new medications for chronic diseases from the Australian Government's Biomedical Translation Fund (BTF) and was able to match this by raising another AU$20 million from other Australian investors. The BTF fund provides companies, like George Health, with venture capital through licensed private sector fund managers.

Terms of Reference

This inquiry will consider the following topics so that Australia continues to be well positioned to access new drugs and novel medical technologies in a timely manner and respond to emerging global trends:

1) The range of new drugs and emerging novel medical technologies in development in Australia and globally, including areas of innovation where there is an interface between drugs and novel therapies;

2) Incentives to research, develop and commercialise new drugs and novel medical technologies for conditions where there is an unmet need, in particular orphan, personalised drugs and off-patent that could be repurposed and used to treat new conditions;

3) Measures that could make Australia a more attractive location for clinical trials for new drugs and novel medical technologies; and

4) Without compromising the assessment of safety, quality, efficacy or cost-effectiveness, whether the approval process for new drugs and novel medical technologies, could be made more efficient, including through greater use of international approval processes, greater alignment of registration and reimbursement processes or post market assessment.

1) The range of new drugs and emerging novel medical technologies in development in Australia and globally, including areas of innovation where there is an interface between drugs and novel therapies.

The George Institute and George Health have developed novel medical technologies including:

- **Join Us: national research register:** Join Us is an easy way for millions of Australians to participate in life-saving health and medical research. It is a secure register that matches participants with research studies addressing Australia's biggest health challenges. Currently, one of the most difficult things about conducting research is finding the right participants. Join Us will help to solve this problem. Through an opt in process by consumers, it will help our world class researchers find answers to medical challenges facing us all – preventing disease, and finding cures and treatments that can benefit ourselves, our families, neighbours and even those we don't know. It will boost research capability in Australia and have long term economic benefits by attracting international studies. Please visit www.joinus.org.au for more information.

- **The Affordable Dialysis System:** 10 million people worldwide live with end-stage kidney disease, and over seven million of them will die because they do not have access to life-saving dialysis or a kidney transplant. This is the need that Ellen Medical Devices and The George Institute aim to address. Our peritoneal dialysis machine can sterilise water in places where water supply may be contaminated by using solar power, can fit in a small suitcase, and runs on a few dollars a day. This machine is an innovative solution to a massive global health problem that can impact the lives of millions of people in low- and middle-income countries. Please visit www.ellenmedical.com/the-device/ for more information.

- **Polypill:** Cardiovascular disease is the leading cause of disease burden globally, and affects people across the geographic and socio-economic spectrum. Although many effective treatments are available, only half the people at risk in high income countries and less than 10 percent of at-risk people in low-income countries are receiving all recommended treatments. To combat this problem, The George Institute has developed a range of low-dose combination therapies. This means that patients only need to take one pill, once a day, to receive the multiple drugs they need to prevent secondary events. These polypills will ensure that more patients take the right pills at the right time, and will help reduce their risk of heart attack and stroke. Please CLICK HERE for more information.

- **FoodSwitch App:** Packaged food products often contain surprisingly high levels of salt, sugar, saturated fat and calories, all of which may contribute to health risks such as heart disease and diabetes. In order to make better choices, people need information about what they are buying, but nutrition information on food labels can be confusing. FoodSwitch was designed to help people make healthier choices by empowering users with information, and suggesting healthier alternatives. This app, currently available in ten countries, is allowing people to take control of their health and improve their well-being through informed decision making. Please visit www.foodswitch.com.au for more information.

- **SMARThealth:** Five billion people worldwide live without reliable access to primary healthcare. In many low- and middle-income countries, health systems face severe resource constraints and workforce shortages, and as a result require innovative healthcare delivery solutions. SMARThealth is a low cost, digital platform that supports clinical decision-making and improves the screening, detection and management of chronic disease in adults. It is currently being used in Australia, China, India and Indonesia and has the potential to transform primary healthcare in resource-poor settings, as it provides an accurate, mobile process for identifying high-risk patients and referring those in urgent need for further care. Please CLICK HERE for more information.

2) Incentives to research, develop and commercialise new drugs and novel medical technologies for conditions where there is an unmet need, in particular orphan, personalised drugs and off-patent that could be repurposed and used to treat new conditions.

The George Institute believes there are several incentives that can be provided by the Australian Government to research, develop and commercialise new drugs and novel medical technologies, particularly for non-communicable diseases. This includes:

- **Supporting early-stage commercialisation:** Early-stage commercialisation is best done via seed funding, proof of concept funding, and investment schemes. Although existing schemes are valuable, they do not address the earlier 'valley of death' stages of health and medical research, development and commercialisation of new drugs and novel medical technologies, that are often under-funded.

- **Investing in low-to-moderate risk developments:** Currently there are low levels of investment for low-to-moderate risk developments. While some funding is available through National Health and Medical Research Council (NHMRC) grants, the investment is not adequate. Additional investment would benefit patients and the system. We recommend investing between AU$5 million to AU$25 million. Without this additional investment, there will be very few options for low-to-moderate risk developments, leading to a missed opportunity for Australia.

- **Helping researchers turn their ideas into reality:** Researchers develop ideas for new drugs and novel technologies as part of their work. In most cases, to further progress, researchers need to become commercial and venture into business. This can be a barrier. The Australian Government can address this barrier by offering:
    - Training, coaching and advice on commercial and business opportunities.
    - Networking events for researchers to meet investors.
    - Financial support, including low or interest free loans.

- **Retaining researchers:** Researchers who become more commercial and business-focused in order to develop new drugs and novel technologies may face a financial barrier should they wish to return to research. The Australian Government can address this burden by offering financial support and incentives for researchers to return.

- **Continuing to invest in health and medical research:** Health and medical research plays an important part in research, development and commercialisation of new drugs and novel medical technologies. Ensuring this vital pipeline requires recurrent funding of the NHMRC, the Medical Research Future Fund (MRFF) and the Biomedical Translation Fund (BTF) at levels consistent or greater than the consumer price index.

- **Continuing to support and enhance the R&D tax incentive scheme:** This is very attractive to overseas Biotechs doing early phase clinical studies and often can be decider as to the country chosen to conduct the studies. Better advertising is needed and clarity around what can and cannot be claimed under the scheme.

3) Measures that could make Australia a more attractive location for clinical trials for new drugs and novel medical technologies.

The George Institute believes there are measures the Australian Government can undertake to be a more attractive location for clinical trials for new drugs and novel medical technologies.

Please refer to the answers provided in the Terms of Reference Point 2 on:

- **Supporting early-stage commercialisation;**
- **Investing in low-to-moderate risk developments**
- **Helping researchers to turn their ideas into reality;**
- **Retaining researchers; and**
- **Continuing to invest in health and medical research.**

Other measures include:

- **Better alignment of funding and programs:** There should be an alignment between Australian jurisdictions and within government departments and agencies:
    - **Inter-jurisdictional:** Australia should centralise ethics approval processes. Despite attempts to centralise, ethics approvals remain driven by institutions, states and territories. A truly centralised ethics approval process would lead to greater efficiencies. In addition, there should be a greater alignment between jurisdictions in relation to funding opportunities. For example, the Commonwealth Government's National Health and Medical Research Council (NHMRC) and Medical research Future Fund (MRFF) grant programs should align with the NSW Office of Health and Medical Research (OHMR) grant programs.
    - **Inter-governmental:** There should also be a greater alignment between government departments and agencies within jurisdictions. For example, Austrade organises the Landing Pad Program, the agency's global service offer for Australian start-ups/scale-ups. The program provides market-ready scaleups with an operational base and customised support for their overseas expansion goals in Singapore, San Francisco, Tel Aviv, Berlin and Shanghai. The Department of Health should play a part in this program.
- **Learning from world-class agencies and programs:** Australia can learn, adopt ideas from and partner with other jurisdictions. Case studies include:
    - **The Victorian Government's LaunchVic:** LaunchVic was established in 2016 by the Victorian Government. It is an independent agency responsible for developing Victoria's start-up ecosystem with a focus on funding, community building and creating global recognition. It has realised two strategic plans. The first, from July 2017 to June 2019, was Growing Victoria's Start-up Community; and the second, from July 2019 to the present, is Building For Growth. LaunchVic funds service providers and programs that address specific gaps and needs in the start-up ecosystem, aligning with its strategic plan. Further information is available at https://launchvic.org/.

- **The Israel Innovation Authority (IIA):** Established in 1965 as the Office of the Chief Scientist, this body was renamed the IIA in 2016. It is an independent, government-funded agency that partners with venture funds (public-private partnerships) to provide practical tools and funding platforms for local and international innovation ecosystems. Its divisions include Start-up Division, Growth Division, Technological Infrastructure, International Collaboration, Advanced Manufacturing and Societal Challenges. IIA invests in early-stage start-up projects that are too risky for private investment. It also undertakes 'reverse innovation', which is to start with challenges and unmet needs, and then calling for innovative solutions. Further information is available at https://innovationisrael.org.il/en/.

- **California, United States:** California is ranked the number one US state for innovation. This is due in large part to having 10 health-related companies from the S&P 500 headquartered in the state. California attracts these innovative companies thanks to its start-up environment, including access to universities, industry, venture capital, and effective transport infrastructure, and the fact that it allows companies to take risks and 'fail safely'. Australia needs to attract the best Australian and global innovative companies if it wants to be the most innovative for clinical trials for new drugs and novel medical technologies.

- **Embrace 'open innovation'**: Open innovation is when businesses, not-for-profits and other non-government organisations source and embrace open ideas. Although open innovation may be in contrast to Intellectual Property Rights (IPR), several of the largest patent holders around the world have embraced the open innovation model. Government should support, incentivise and facilitate open innovation between universities, medical research institutes and the corporate and private sector, including through industry placements.

4) Without compromising the assessment of safety, quality, efficacy or cost-effectiveness, whether the approval process for new drugs and novel medical technologies, could be made more efficient, including through greater use of international approval processes, greater alignment of registration and reimbursement processes or post market assessment.

The George Institute believes the following can be undertaken to make the approval process for new drugs and novel medical technologies more efficient, without compromising safety, quality, efficacy or cost-effectiveness. This includes:

- **Streamlining approval processes:**
  - Implement processes for fast-tracking new drug and/or novel medical technology by building earlier regulatory approvals into clinical trial guidelines and requirements.
  - Introduce and maintain priority approval and review pathways for identified disease areas or conditions. For example, COVID-19, cardiovascular disease and diabetes.
  - Revive failed drugs that were developed, but found not to be as, or more, effective than existing treatments and therefore abandoned. Failed drugs have the potential to be repurposed for different conditions.

- **Harmonisation between international jurisdictions:** A key challenge for companies developing new treatments and bringing them to market is the different regulatory requirements, approvals and timelines of international jurisdictions. This often leads to an increase and duplication in costs and delays. Agencies include the Australian Therapeutic Goods Administration (TGA), the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA). There have been several key initiatives to harmonise the international regulatory landscape and simplify processes by eliminating the need for country-specific tests and studies, and increasing the consistency of interpretation of data. This harmonisation has helped reduce costs for pharmaceutical and biotech companies by enabling them to develop one single set of data and documentation to be submitted to several different countries. While Australia is an important market, it represents a small percentage of the global market, and should continue to harmonise with the international community. We note and support the TGA International Engagement Strategy 2016-2020, and look forward to it being updated in 2021. The more the TGA and Pharmaceutical Benefits Advisory Committee (PBAC) are part of international assessments of efficacy, safety and cost-effectiveness, the easier the process and the better the outcome.

- **Government investment:** The government should provide training, guidance and mentoring for researchers on the process of drug and device approval processes. In addition, financial support should be provided, especially to not-for-profit organisations, who are going about the process of drug and device approval processes.

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