Cell & Gene Catalyst submission in response to the *Unleashing the Potential of our Healthcare Workforce – Scope of practice review*

TO: Department of Health and Aged Care
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From: Cell & Gene Catalyst, a joint venture of AusBiotech and Medicines Australia

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About the Cell & Gene Catalyst
The Cell & Gene Catalyst (Catalyst) is a national joint venture of two industry peak bodies, AusBiotech and Medicines Australia. To accelerate and grow Australia's cell and gene therapy ecosystem, AusBiotech and Medicines Australia established the national joint venture, the Catalyst, led by an Expert Steering Group from Catalyst partner organisations CSL Behring, Cell Therapies, Therapeutic Innovation Australia, Novartis Australia & New Zealand, Pfizer and Roche Australia.

AusBiotech is the Australian representative body for one of Australia's most innovative industries with a well-connected network of over 3,000 members in the life sciences industry, which includes biotherapeutics, medical technology (devices and diagnostics), food technology and agricultural biotechnology sectors.

Medicines Australia (MA) leads the research-based medicines industry of Australia. MA members discover, develop and manufacture prescription pharmaceutical products, biotherapeutic products and vaccines that bring health, social and economic benefits to Australia. Members invest in Australian medical research and take local discoveries and developments to the world.

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Introduction

The Cell & Gene Catalyst welcomes the opportunity to submit a response to the Department of Health and Aged Care's consultation paper on Unleashing the Potential of our Healthcare Workforce – Scope of practice review.

Australia has a substantial life sciences and biotechnology sector, which is consistently ranked as one of the top countries for biotechnology innovation globally when adjusted for population. Industry employs almost 100,000 Australians and consists of more than 1,425 biotechnology companies. Around 80 per cent of these industry companies are small to medium enterprises (SMEs) working to commercialise their research, with an increasing number developing new and novel technologies such as cell and gene therapies (CGT).

The rapid growth of Australia's cell and gene industry means greater opportunities to treat people in Australia who live with debilitating inherited diseases and cancers. Importantly, this rapidly expanding industry will create new jobs in for Australia's diverse, skilled workforce. This will boost Australia's health and economy and secure our position as a leader in the Asia-Pacific region and on the broader international stage.

This submission represents Catalyst stakeholders actively engaged in delivering social and economic benefits to Australia through the commercialisation of biotechnologies and medical technologies. Responses have been framed around the Department's questions outlined in the consultation paper. We emphasise that successful implementation of the Scope of Practice review's recommendations will require robust accountability mechanisms, clear lines of responsibility and detailed steps to delivering impact.

The Cell & Gene Catalyst makes the following recommendations:

Recommendation 1: That the Scope of Practice review and proposed reforms be informed by the objectives and priority actions in the *Strategic Roadmap for Regenerative Medicine in Australia* (page 15, Health System Readiness; page 31, Talent Priority Actions) and consider the entire value chain in the *Regenerative Medicine Value Chain* report (page 9, Figure 2, part E; page 11, first para; page 57, Patient Delivery).

Recommendation 2: That the Pharmacy Board of Australia work with the CGT sector to develop standards and guidelines for cell and gene therapies for dissemination to pharmacy professionals.

Recommendation 3: That the Medical Board of Australia recognises cell and gene therapies as a medical specialty and certifies specialised training programs for CGT in clinical settings.

Recommendation 4: Provide incentives to education providers to develop specialised education and training resources to ensure the primary care workforce is appropriately trained in the delivery, monitoring and ongoing care of individuals who have received cell and gene therapies.

Recommendation 5: Government support is provided for the development of accredited education and training of current primary healthcare professionals and primary care service providers in cell and gene therapy technologies and GXP compliance.

Ensuring the review considers Australia's growing cell and gene industry providing access to new therapies

To ensure everyone in Australia has ready access to world-class treatments such as cancer immunotherapies, cell and gene therapies (CGT) and gene-editing therapeutics, there is an urgent need to grow our capacity and capabilities across the entire cell and gene industry value chain as published in

AusBiotech's Regenerative Medicine Value Chain report.[i] The Strategic Roadmap for the Regenerative Medicine Sector[ii] outlines we need to streamline the regulatory environment for the application of CGT developed in Australia and overseas, grow the CGT manufacturing sector, and educate and train our healthcare and manufacturing workforce.

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Developing speciality qualifications, standards and guidelines in pharmacy and medicine

To facilitate successful delivery and application of advanced therapeutics within a modern health system, Australia needs to increase the capacity and capabilities of the healthcare workforce. This includes an urgent need for specialised medical professionals with deep knowledge in treating and managing individuals with cell and gene therapies. This is required since there are multiple delivery modes for these advanced therapeutics and each situation requires significant CGT knowledge, robust standards and clear guidelines to minimise risks and ensure a successful outcome.

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Increasing education and training for the healthcare workforce and service providers

Supporting the development of specialised qualifications (R3), new and ongoing education and upskilling will be needed. Incentivising education providers to develop targeted courses and speciality degrees will provide students' cutting-edge knowledge and skills in CGT at the vocational and tertiary levels. This includes targeted courses and training to increase understanding and skills in GXP compliance, such as good clinical practice (GCP), good manufacturing practice (GMP), good laboratory practice (GLP) and good pharmacovigilance practice (GVP). This will ensure clinical application and delivery of clinical grade CGT in Australian are in accord with international standards and best practice.

Raising the baseline knowledge and skills in CGT of general practitioners and healthcare service providers who will contribute to the ongoing monitoring, care and support of treated individuals will also be critical. Industry-led education and training in cell and gene therapies will enable the development of a modern healthcare system that can deliver cutting-edge treatments and world-class care.

Recommendation 4: Provide incentives to education providers to develop specialised education and training resources to ensure the primary care workforce is appropriately trained in the delivery, monitoring and ongoing care of individuals who have received cell and gene therapies.

Recommendation 5: Government support is provided for the development of accredited education and training of current primary healthcare professionals and primary care service providers in cell and gene therapy technologies and GXP compliance.

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[i] Regenerative Medicine Value Chain (2021): https://www.ausbiotech.org/documents/item/664.
[ii] Strategic Roadmap for the Regenerative Medicine Sector (2021): https://www.ausbiotech.org/documents/item/677.