FOR IMMEDIATE RELEASE

HEALTH SCIENCES AUTHORITY
PRESS RELEASE
6 NOVEMBER 2020

PUBLIC CONSULTATION ON THE PROPOSED REGULATION FOR CELL, TISSUE AND GENE THERAPY PRODUCTS UNDER THE HEALTH PRODUCTS ACT

The Health Sciences Authority (HSA) invites public feedback on the proposed regulation for cell, tissue and gene therapy products (CTGTP), a new category of health products. The public consultation will run from 6 November 2020 to 27 November 2020.

2 The area of CTGTP is a rapidly evolving field where cells and tissues can be engineered to grow healthy and functional tissues to reconstruct, regenerate or repair damaged tissues or organs, or where new genes are introduced into the body to treat or cure diseases. CTGTP has the potential to transform the current practice of medicine and offer potential cures for chronic and debilitating diseases. HSA is proposing to include the new category of CTGTP in the First Schedule to the Health Products Act.

3 The regulation of CTGTP will:

(i) facilitate patients' access to medically important therapies that meet the appropriate standards of safety, efficacy and quality; and

(ii) provide a fit-for-purpose regulatory framework that supports product development and facilitates product commercialisation.

4 The key proposed regulations include:

- **Definition of 'CTGTP'** based on the presence of stem cells, tissues and genes, and their purpose;
- **Risk-based regulatory approach** for product registration and dealer licensing, based on the degree of manipulation (minimal or more than minimal), intended use (homologous or non-homologous use) and whether it is a

combination product (whether combined with medical devices or therapeutic products), with Class 1 CTGTP being lower risk, and Class 2 CTGTP being higher risk;

- **Requirements that are unique to CTGTP** include having a traceability system to enable bi-directional tracking of CTGTP from its source up to the administration of the product to the patient and vice versa, and maintaining the records of traceability for 30 years after the expiry of the product.

VIEWS SOUGHT

5 HSA welcomes feedback on the proposed definition and regulations for CTGTP. The feedback will help in refining the proposed regulatory framework before it is finalised for implementation.

6 The public consultation document and draft legislations are available on the HSA website (hsa.gov.sg) and REACH portal (reach.gov.sg). Please provide your feedback by **27 November 2020 (Friday)**. Scan the QR code below or click HERE to access the feedback form.

https://go.gov.sg/ctgtpconsult-2020

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About the Health Sciences Authority (HSA)

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood

Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit http://www.hsa.gov.sg/.

For more updates on public health and safety matters, follow us on Twitter at www.twitter.com/HSAsg.

About HSA's Health Products Regulation Group

The Health Products Regulation Group (HPRG) of HSA ensures that drugs, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards. It contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework.