APPENDIX 2 PRE-MARKET CONSULTATION FOR CLASS 2 CELL, TISSUE OR GENE THERAPY PRODUCT REGISTRATION

1. ARRANGING FOR PRE-MARKET CONSULATION

Each consultation is limited to one single product registration application and up to 1 hour in duration. For booking an appointment, you can write to us at HSA_CTT_Enquiry@hsa.gov.sg with the proposed date and time. When the date and time is confirmed, you can submit the application using the form, "Application for Pre-Market Consultation for Class 2 Cell, Tissue or Gene Therapy Product Registration".

2. FEES

As the fees may be subject to revision from time to time, applicants are advised to visit the HSA website for updated information on fees. The application fee is non-refundable.

3. DOCUMENTS SUBMISSION

1. Please complete the pre-market consultation form in this appendix.
2. Please ensure that all fields are completed. Incomplete forms will not be accepted.
3. Please send the completed form and documents compiled for pre-market consultation for product registration to HSA_CTT_Enquiry@hsa.gov.sg at least **30 working days** before the meeting date, with the subject of the email in the following format: **"Cell, Tissue or Gene Therapy Product Pre-market Consultation <Appointment date> Ref: <Booking Reference>"**.
4. The guidance document for product registration is for Class 2 CTGTP and is available at https://www.hsa.gov.sg/ctgtp/guidance-documents.

4. NOTE TO APPLICANT

This pre-market consultation is to verify the completeness and appropriateness of the documents. This is not a scientific evaluation of the product. The consultation is not an iterative process and this is does not guarantee for product registration.

Advice given is based on the information provided prior to the meeting. Any changes made to the documents or availability of new information after the meeting may affect the advice given at the meeting.

REVISION HISTORY

Guidance Version (Publish Date)
ATPB-GN-002-000 (March 2021)

REPUBLIC OF SINGAPORE
HEALTH SCIENCES AUTHORITY

HEALTH PRODUCTS ACT
CHAPTER 122D

PRE-MARKET CONSULTATION FORM

Please refer to the latest guidance on HSA website before filling up the form.

Booking Reference Number:		**Date of Appointment:**	
		Time of Appointment:	

ATTENDEE PARTICULARS

	Name of Attendee(s)	Designation/ Company Name
1.		
2.		
3.		
4.		
5.		
6.		

MEETING AGENDA

☐ **General registration requirements**

☐ **Others:** *(please specify)*

Brief Summary:

- *Summaries of the quality, non-clinical and non-clinical data (e.g. Overviews)*
- *Clear and concise questions, or areas of concerns you wish to discuss during the consultation session.*
- *Separately, please attach the supporting information/ documents in relation to the questions to be discussed. Information can be provided in any format, e.g. PowerPoint slides, summary copies etc. Please keep your supporting information targeted and focused on the questions. Please note that submission of extraneous information can be counterproductive.*

Have you enquired on this Cell, Tissue or Gene Therapy Product previously?	☐ No ☐ Yes, please state the reference number of the previous enquiry: *(You may attach the email communications of the previous enquiry, where necessary)*
PRODUCT INFORMATION	
Name of Product Owner	
Product Name *(Including dosage form & strength)*	
Name & Strength of Active Substance(s):	
Proposed Indication(s):	
Proposed Dosing Regimen: ***(****Including patient population)*	
Registration Status in Other Countries:	
Planned Submission in Other Countries:	
Projected Date of Submission to HSA	
DECLARATION	
☐	I hereby attest that the information provided is accurate, authentic and complete.