REPUBLIC OF SINGAPORE HEALTH SCIENCES AUTHORITY HEALTH PRODUCTS ACT CHAPTER 122D



PRE-MARKET CONSULTATION FORM

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	Please	refer to the lates	t guidance d	on <u>HSA website</u> before fill	ing up the form.		
Booking Reference Number:				Date of Appointment:			
				Time of Appointment:			
ATTENDEE PARTICULARS							
Name of Attendee(s)		Designation/ Company Name		Email	Email Address		
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. 							
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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			
Produ	ict Name (Including dosage form & strength)			
Name	& Strength of Active Substance(s):			
Propo	esed Indication(s):			
Proposed Dosing Regimen: (Including patient population)				
Registration Status in Other Countries:				
Planned Submission in Other Countries:				
Proje	cted Date of Submission to HSA			
DECLARATION				
i	I hereby attest that the information provided is accurate, authentic and complete.			

Form Version (Publish Date) FORM-ATPB-1-4 Rev 001 (Oct 2024)