Annex A.11 Biotech Companies

Applicant	Background and Decision
Company A *(MB applicant) (2022)* Rule reference: MB Rule 18A.01	*Background* 1. Company A was a biotech applicant under MB Chapter 18A. It had identified Product X (a biologic product) as one of its Core Products for the purpose of the proposed listing. 2. Company A conducted the Phase 1 clinical trial on Product X under the Therapeutic Goods Administration ("**TGA**") in Australia ("**TGA Trial**"). Subsequently, Company A decided to conduct the global pivotal Phase 2/3 clinical trials on Product X in multi-centres, including the European Union and Mainland China markets. Prior to the completion of the TGA Trial, Company A requested a rapid scientific advice (RSA) from the European Medicines Agency ("**EMA**") and initiated the investigational new drug (IND) application with the National Medical Products Administration ("**NMPA**"). 3. Company A submitted the clinical trial designs and data for the TGA Trial and the global pivotal Phase 2/3 clinical trials on Product X to both the EMA and the NMPA. After reviewing the materials on the clinical data of the TGA Trial and protocol of the global pivotal Phase 2/3 clinical trials, both the EMA and the NMPA confirmed their acknowledgement and acceptance of the results of the TGA Trial and that they had no objection for Company A to progress to the pivotal global Phase 2/3 clinical trials on Product X. 4. Subsequently, Company A had obtained approval from both the EMA and the NMPA to commence the global pivotal Phase 2/3 clinical trials on Product X. *Decision* 5. Based on the specific facts and circumstances, the Exchange was satisfied that the TGA Trial (which was not a clinical trial regulated by a Competent Authority recognised under MB Chapter 18A) on Product X met the "Clinical Trial" milestone requirements of a Core Product under **Chapter 2.3** given both the EMA and the NMPA (both being Competent Authorities under MB Chapter 18A) had: (i) Reviewed and taken into account the clinical trial design and data of the TGA Trial in granting their approval for Company A to commence the global pivotal Phase 2/3 clinical trials on Product X; and (ii) Confirmed their acknowledgement and acceptance of the results of the TGA Trial and that they had no objection for Company A to progress to the pivotal global Phase 2/3 clinical trials on Product X based on the clinical results of the TGA Trial. 6. Such conclusion was specifically related to Product X and did not result in the TGA being generally recognised as a Competent Authority for the purpose of MB Chapter 18A, and/or a clinical trial conducted under the TGA being generally accepted as a trial regulated by a Competent Authority.