PART C: CHECKLIST ON DOSSIER REQUIREMENTS FOR MIV-2 (DO-AND-TELL) VARIATION

Declaration of the product registrant for MIV-2 Do-and-Tell

I hereby declare that:

- All changes submitted are categorised as MIV-2 Do-and-Tell, and no other changes have been included in this application.
- The change(s) will not adversely affect the quality, efficacy and safety of the therapeutic product concerned.
- All information provided by me in this MIV-2 Do-and-Tell is true and accurate.

Name	Signature	Date

C17 Change in Packaging Material Not in Contact with Drug Product	
C	1. For change of packaging material not in contact with drug product, such as colour of flip-off caps, colour code rings on ampoules, change of needle shield. 2. The change does not concern a part of the packaging material, which affects the delivery, use, safety or stability of the drug product.
D	1. Amendment of the relevant section(s) of the dossier (presented in the CTD format), including revised product labelling as appropriate.

C18 Change of Product Owner or Change in Name and/or Address (for example: postal code, street name) of Product Owner	
C	1. The product registrant remains unchanged. 2. The manufacturing site remains unchanged. 3. There are no other variation applications pending approval. All changes should be submitted and approved before the registration transfer takes place.
D	**For change of product owner:** 1. Revised drafts of the package insert and labelling incorporating the proposed variation (where applicable). 2. A declaration on the transfer of ownership between the old product owner and new owner.

	3. An official letter from the new product owner declaring the change and authorising the local registrant to be responsible for the product registration. 4. If the new product owner is not the manufacturer of the drug product, an official letter by the new product owner authorising the manufacturer to manufacture the drug product on its behalf. **For change of name and/or address of product owner:** 5. Revised drafts of the package insert and labelling incorporating the proposed variation (where applicable). 6. An official letter from the product owner declaring the change and authorising the local registrant to be responsible for the product registration.

C19 Change in Ownership of Manufacturer	
C	1. The manufacturing site remains unchanged. 2. No other changes except for the change in ownership of manufacturer.
D	1. Revised drafts of the package insert and labelling incorporating the proposed variation (where applicable). 2. A letter of justification on the transfer of ownership, such as a valid GMP certificate. 3. An official letter stating the transfer of ownership from old manufacturer to the new manufacturer (where applicable). 4. In case of a contract manufacturer, an official letter from the product owner declaring the change and authorising the new manufacturer to manufacture the drug product(s) on its behalf.

C20 Change of Name or Address (for example: postal code, street name) of Manufacturer of Drug Product	
C	1. The manufacturing site remains unchanged. 2. No other changes except for the change of the name and/or address of a manufacturer of the drug product. 3. Not applicable to the case involving a change in ownership of the manufacturer. For a change in ownership of manufacturer, refer MIV-2 C19.
D	1. Revised drafts of the package insert and labelling incorporating the proposed variation (where applicable). 2. A valid GMP certificate, a CPP which covers the GMP certification or an official document from a relevant authority confirming the new name and/or address. 3. An official letter from the product owner authorising the manufacturer with the new name/address to manufacture the drug product.

C21 Change of Name or Address (for example: postal code, street name) of Company or Manufacturer Responsible for Batch Release	
C	1. The manufacturer of the drug product remains unchanged. 2. The batch release site remains unchanged. 3. Not applicable to the case involving a change in ownership of the manufacturer. For a change in ownership of manufacturer, refer MIV-2 C19.
D	1. Revised drafts of the package insert and labelling incorporating the proposed variation (where applicable). 2. A valid GMP certificate, a CPP which covers the GMP certification or an official document from a relevant authority confirming the new name or address (where applicable). 3. An official letter from the product owner authorising the company/manufacturer with the new name/address that is responsible for batch release. 4. A declaration from the product registrant that the change does not involve a change of batch release site.

C22 Change of Name and/or Address (for example: postal code, street name) of Manufacturer of Drug Substance	
C	1. The manufacturing site of the drug substance remains unchanged. 2. No other changes except for the change of the name and/or address of a manufacturer of the drug substance.
D	1. Updated information of the manufacturer of the drug substance. 2. An official document/evidence confirming the new name and/or address.

C23 Withdrawal/Deletion of Alternative Manufacturer(s) for Drug Substance and/or Drug Product and/or Packager and/or batch releaser	
C	1. An alternative manufacturer is registered.
D	1. Reason for withdrawal/deletion.

C24 Change of Specification of Excipient to Comply with Pharmacopoeia	
C	1. Applicable to compendial specifications only. 2. Change is made to comply with an update of the relevant monograph of the compendium or from one recognised pharmacopoeia to another. 3. Pharmacopoeia recognized by HSA: United States Pharmacopeia, European Pharmacopoeia, British Pharmacopoeia and Japanese Pharmacopoeia.

D	1. Specification of the excipient. 2. Tabulation of the approved and proposed specification of the excipient(s) with changes highlighted. 3. Certificate of analysis or batch analysis of the excipient(s) for all tests in the new specification of at least two batches. 4. A declaration that the change has no impact on the manufacturing process and quality of the drug product.

C25 Deletion of Pack Size for Drug Product	
C	1. The remaining pack sizes are adequate to accommodate the dosing regimen as per the approved product labelling. 2. For addition of pack size for sterile drug products, refer to MIV-1 B6. For a change in the outer carton pack size, refer to MIV-2 C11.
D	1. Revised drafts of the package insert and labelling incorporating the proposed variation (where applicable). 2. Reason for deletion.

C26 Change of Batch Numbering System	
C	1. The manufacturing site remains unchanged.
D	1. Description of the revised batch numbering system. 2. An official letter stating the commencement date of the change.

C27 Change of Name of Quality Control (QC) Testing Laboratory	
C	1. No other changes except for the change of the name and/or address of the approved laboratory(ies) for stability tests or any quality control tests.
D	1. Updated information of the testing laboratory. 2. An official letter from the product owner authorising the testing laboratory with the new name/address.

C28 Addition or Replacement of Site Responsible for Quality Control Testing Laboratory	
C	1. For addition or replacement of the approved laboratories for release and/or stability test that is of compendial method.

	2. For addition or replacement of the approved laboratories for release and/or stability tests not covered in MIV-1 B10.
D	1. Approved release and shelf life specification. 2. Analytical procedures to be carried out at the proposed site. 3. Certificate of analysis or batch analysis data (in a comparative tabular format) of at least two production batches tested at the approved and proposed site.

C29 Update of Product Labelling • Changes to non-English language text (e.g. Chinese). • Rearrangement/re-formatting of text/images without any change in information. • Addition/change of labelling intended for foreign markets (i.e. shared pack), e.g. other countries' registration/ licence no./ poison labels/foreign language text in package insert. • Addition/update/deletion of barcode / QR code for logistic purposes.	
C	1. Product labelling refers to Package Insert (PI), Patient Information Leaflet (PIL), unit carton label, inner label and/or blister strips. 2. The change is not an MIV-1 and does not contain promotional information.
D	1. Current approved product labelling. 2. Proposed product labelling, a clean and annotated version highlighting the changes made. 3. Relevant document/reference to support the changes (where applicable).

REVISION HISTORY

Guidance Version (Publish Date)

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