

## **PRISM enhancements (effective 02 December 2014)**

**This guide provides a preview of the new drop down listing in PRISM for:**

- 1. MIV-1 application**
- 2. MIV-2 application**
- 3. Global change affecting multiple product licenses/pending applications**

## MIV-1 application

- Section 0.4 Amendment summary is now replaced with a drop-down listing of Appendices 15 (for Chemical Drugs) and 16 (for Biologic drugs) of the Guidance.
- Please select the applicable MIV-1 Checklists from the drop-down list under 0.4 MIV Checklist Number (Primary change)
- Only one MIV-1 Checklist per application is allowed for primary change.

The screenshot displays the '0. Licence/Permit/Certificate/Listing Summary' section of a form. It includes fields for '0.1 Licence/Permit/Certificate/Listing No.', '0.2 Start Date', and '0.3 Expiry Date'. The '0.4 MIV Checklist Number (Primary Change):\*' field is highlighted with a red box and contains a dropdown menu with 'Please Select One' selected. Below this, the '0.5 MIV Checklist Number (Secondary Change(s)):' section features two columns: 'Available MIV Checklist' and 'Selected MIV Checklist'. The 'Available MIV Checklist' column contains a list of 22 items, including 'B7 Chg of Spec of DS [CEP not Avail] / DF', 'B8 Chg of Spec of DS [CEP Avail]', 'B9 Chg of Batch Size of Sterile DP', 'B10 Chg of Batch Size of Non-sterile DP', 'B11 Major Chg in Mfg Proc for DP', 'B12 Qual or Quan Chg of Excipient', 'B13 Quan Chg in Coat W or Caps Shell W', 'B14 Chg in Pri Pac Mtl for Sterile Pdt', 'B15 Chg or Addn of Size/Shape of CCS f', 'B16 Inclusion or Repl of Solvent/Diluent', 'B17 Chg of Shelf-life of DP', 'B18 Chg of Storage Conds of DP', 'B19 Addn or Chg of Score/Break Line of', 'B20 Chg of Sterility Testing to Parametri', 'B21 Imp New or Extension Approved De', 'B22 Chg of Content of Pdt Labelling', 'C1 Chg of DP Name', 'C2 Chg of Pdt Labelling', 'C3 Addn or Repl of Co or Party Resp for', and 'C4 Chg of Batch Size of DS [CEP is not A]'. The 'Selected MIV Checklist' column is currently empty. Navigation arrows are visible between the two columns.

- In situations when an application contains consequential changes, the main change is to be reflected as the primary change in “0.4 MIV Checklist Number (Primary Change)” and each consequential change should be entered in “0.5 MIV Checklist Number (Secondary Change[s])” in the PRISM application form.
- If you wish to select multiple changes at one go, you can press on Ctrl button and mouse click on those that you wish to choose and click on the right arrow. For de-select, you can do the same on the right and click on the left arrow to remove.

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- **Non-consequential MIV-1 changes are strictly not allowed. For instance, for a CMC MIV-1 application, MIV-1 updates to the product labelling unrelated to CMC changes will not be accepted. However, MIV-2 changes are still allowed to ride on an MIV-1 application as per status quo.**
- For variation changes not covered under Appendices 15 and 16, e.g., those provided as a result of MIV Inquiries, please select “Others” from the drop-down list and indicate the relevant details in the text box provided.

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0.2 Start Date:					
0.3 Expiry Date:					
0.4 MIV Checklist Number (Primary Change):*	<div style="border: 1px solid red; padding: 5px;">           Others <span style="float: right;">▼</span>            Please specify:            Please enter details of MIV change, for changes not covered in Appendices 15 and 16         </div>				
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0.6 Remarks: *	<div style="border: 2px solid red; padding: 5px;"> <p>This text box will only be activated if "Others" is chosen for Section 0.5</p> </div>				

## MIV-2 application

- PRISM interface is similar to that for MIV-1 applications illustrated above. Key difference is that only MIV-2 checklists are available for selection.
- Multiple MIV-2 Checklists may be submitted in one application (select one checklist under 0.4, and other checklists under 0.5)

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0.1 Licence/Permit/Certificate/Listing No.:	
0.2 Start Date:	
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0.4 MIV Checklist Number (Primary Change):*	Please Select One
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**Global change affecting multiple product licenses/pending applications**

- If this change affects other product licences, or if there are pending related applications which you would like to bring to the attention of HSA officers, please select radio button “Y” for section 0.8, and enter relevant details in Section 0.9. e.g., PRISM application number, licence numbers.

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0.1 Licence/Permit/Certificate/Listing No.:	SIN910282P																																										
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0.9 If yes, please provide relevant Licence No or Application No.:	pending MIV application for SINxxxxxP (app no: T14xxxxxxZ)																																										