INSPECTORATE (INS)

Exception type	Addition	**SAHPRA code**	INS_ A.1	
SAHPRA classification		IAin		
Code description		Change in the name and/or address of the marketing authorisation holder.		
Condition		The marketing authorisation holder must remain the same legal entity.		
Documentation		1. A formal document from a relevant official body in which the new name or new address is mentioned. 2. Revised product information.		

Exception type	Addition	**SAHPRA code**	INS_A.5.a & INS_A.5.b	
SAHPRA classification		IAin		
Code description		INS_A.5.a: Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites). The activities for which the manufacturer/importer is responsible include batch release INS_A.5.b: Change in the name and/or address of a manufacturer/importer of the finished product (batch release or quality control testing sites). The activities for which the manufacturer/importer is responsible do not include batch release.		
Condition		The manufacturing site undergoing the name and/or address change and all manufacturing operations must remain the same.		
Documentation		1. Copy of the modified manufacturing authorisation, if available; or a formal document from a relevant official body or if not available, from a Regulatory Agency in which the new name and/or address is mentioned. 2. If applicable, amendment of the relevant section(s) of the dossier including revised product information as appropriate.		

Exception type	Addition	**SAHPRA code**	INS_ A.7	
SAHPRA classification		IAin		

Code description	Deletion of manufacturing sites for an active substance (API), intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)
Conditions	1. There should at least remain one site/manufacturer, as previously authorised, performing the same function as the one(s) concerned by the deletion. Where applicable at least one manufacturer responsible for batch release that is able to certify the product testing for the purpose of batch release. 2. The deletion should not be due to critical deficiencies concerning manufacturing.
Documentation	1. The variation application form should clearly outline the 'present' and 'proposed' manufacturers as listed in section 2.5 of the application form for marketing authorisations. 2. 2. Amendment of the relevant section(s) of the dossier including revised product information as appropriate.

Exception type	Addition	**SAHPRA code**	INS_B.II.b.1.e & INS_B.II.b.1.f	
SAHPRA classification		Type IB		
Code description		Replacement or addition of a FPP manufacturing site for part or all of the manufacturing process of the finished product		
Conditions		1. Satisfactory inspection in the last 3 years must have been conducted by SAHPRA or a member of PIC/S or a country with a GMP MRA between said country's regulatory authority and SAHPRA 2. Site appropriately authorised (to manufacture the pharmaceutical form or product concerned). 3. The product concerned is not a sterile product. 4. The product concerned is not a biological/ immunological medicinal product. <u>Please note the revision to condition 2</u>: An appropriate authorization refers to a satisfactory inspection conducted in the last 3 years by a member of PIC/S or a country with a GMP MRA between said country's regulatory authority and SAHPRA		

	NB: Please note that SAHPRA Inspectorate reserves the right to reject or approve the inspection outcome from the inspection conducted by an Authority in which a GMP MRA with SAHPRA exists.
Documentation	1. Proof that the proposed site is appropriately authorized for the pharmaceutical form of the product concerned. 2. Applicants are to submit a resolution letter (for local sites), certificate of GMP compliance and, a manufacturing license issued within the last 3 years by SAHPRA or an authority in which a GMP MRA with SAHPRA exists (i.e., a PIC/S member state, ZAZIBONA work-sharing agreement or WHO PQ). 3. The variation application form should clearly outline the 'present' and 'proposed' finished product manufacturers as listed in section 2.5 of the application form. 4. SAHPRA's Quality (PEM) Approval or Recommendation letter

Exception type	Alteration	**SAHPRA code**	INS_ B.II.b.1.a & INS_ B.II.b.1.b	
SAHPRA classification		Type IAin		
Code description		Replacement or addition of a FPP manufacturing site for part or all of the manufacturing process of the finished product		
Conditions		1. Satisfactory inspection in the last 3 years must have been conducted by SAHPRA or a member of PIC/S or a country with a GMP MRA between said country's regulatory authority and SAHPRA 2. Site appropriately authorized (to manufacture the pharmaceutical form or product concerned). 3. The product concerned is not a sterile product. 4. The product concerned is not a biological/ immunological medicinal product. <u>Please note the revision to condition 2</u>: An appropriate authorization refers to a satisfactory inspection conducted in the last 3 years by a member of PIC/S or a country with a GMP MRA between said country's regulatory authority and SAHPRA NB: Please note that SAHPRA Inspectorate reserves the right to reject or approve the inspection outcome from the inspection conducted by an Authority in which a GMP MRA with SAHPRA exists.		
Documentation		1. Proof that the proposed site is appropriately authorized for the pharmaceutical form of the product concerned. 2. Applicants are to submit a resolution letter (for local sites), certificate of GMP compliance and, a manufacturing license issued within the last 3 years by SAHPRA or an		

	authority in which a GMP MRA with SAHPRA exists (i.e., a PIC/S member state, ZAZIBONA work-sharing agreement or WHO PQ). 3. The variation application form should clearly outline the 'present' and 'proposed' finished product manufacturers as listed in section 2.5 of the application form. 4. SAHPRA's Quality (PEM) Approval or Recommendation letter (for INS_ B.II.b.1.b only)

Exception type	Alteration	**SAHPRA code**	INS_B.II.b.2a; INS_B.II.b.2.c.1 & INS_B.II.b.2.c.2	
SAHPRA classification		Type IAin		
Code description		INS_B.II.b.2a: Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place. INS_B.II.b.2.c.1: Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing. INS_B.II.b.2.c.2: Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing.		
Conditions		1. Satisfactory inspection in the last 3 years must have been conducted by SAHPRA or a member of PIC/S or a country with a GMP MRA between said country's regulatory authority and SAHPRA 2. Site appropriately authorized (to manufacture the pharmaceutical form or product concerned). 3. The product is not a biological/immunological medicinal product. 4. Method transfer from the old to the new site or new test laboratory has been successfully completed. <u>Please note the revision to condition 2</u>: An appropriate authorization refers to a satisfactory inspection conducted in the last 3 years by a member of PIC/S or a country with a GMP MRA between said country's regulatory authority and SAHPRA NB: Please note that SAHPRA Inspectorate reserves the right to reject or approve the inspection outcome from the inspection conducted by an Authority in which a GMP MRA with SAHPRA exists.		
Documentation		1. Proof that the proposed site is appropriately authorized for the pharmaceutical form of the product concerned.		

	2. Applicants are to submit a resolution letter (for local sites), certificate of GMP compliance and, a manufacturing license issued within the last 3 years by SAHPRA or an authority in which a GMP MRA with SAHPRA exists (i.e., a PIC/S member state, ZAZIBONA work-sharing agreement or WHO PQ). 3. The variation application form should clearly outline the 'present' and 'proposed' finished product manufacturers as listed in section 2.5 of the application form.

Exception type	Alteration	**SAHPRA code**	INS_B.II.b.2.b & INS_B.II.b.2c.3	
SAHPRA classification		Type II		
Code description		INS_B.II.b.2.b: Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method. INS_B.II.b.2c.3: Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Including batch control/testing for a biological/ immunological product and any of the test methods performed at that site is a biological/immunological/immunochemical method.		
Conditions		1. Satisfactory inspection in the last 3 years must have been conducted by SAHPRA or a member of PIC/S or a country with a GMP MRA between said country's regulatory authority and SAHPRA 2. Site appropriately authorised (to manufacture the pharmaceutical form or product concerned). 3. Method transfer from the old to the new site or new test laboratory has been successfully completed. <u>Please note the revision to condition 2</u>: An appropriate authorization refers to a satisfactory inspection conducted in the last 3 years by a member of PIC/S or a country with a GMP MRA between said country's regulatory authority and SAHPRA NB: Please note that SAHPRA Inspectorate reserves the right to reject or approve the inspection outcome from the inspection conducted by an Authority in which a GMP MRA with SAHPRA exists.		
Documentation		1. Proof that the proposed site is appropriately authorised for the pharmaceutical form of the product concerned. 2. Applicants are to submit a resolution letter (for local sites), certificate of GMP compliance and, a manufacturing license issued within the last 3 years by SAHPRA or an authority in which a GMP MRA with SAHPRA exists (i.e., a		

	PIC/S member state, ZAZIBONA work-sharing agreement or WHO PQ). 3. The variation application form should clearly outline the 'present' and 'proposed' finished product manufacturers as listed in section 2.5 of the application form. 4. SAHPRA's Biological Quality (PEM) Approval or Recommendation letter .

Exception type	Alteration	**SAHPRA code**	INS_ B.II.b.1.c & INS_ B.II.b.1.d	
SAHPRA classification		Type II		
Code description		INS_ B.II.b.1.c: Replacement or addition of a FPP manufacturing site for part or all of the manufacturing process of the finished product. A site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/immunological medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes. INS_ B.II.b.1.d: Replacement or addition of a FPP manufacturing site for part or all of the manufacturing process of the finished product. A site which requires an initial or product specific inspection.		
Conditions		1. Satisfactory inspection in the last 3 years must have been conducted by SAHPRA or a member of PIC/S or a country with a GMP MRA between said country's regulatory authority and SAHPRA 2. Site appropriately authorised (to manufacture the pharmaceutical form or product concerned). 3. Method transfer from the old to the new site or new test laboratory has been successfully completed. <u>Please note the revision to condition 2</u>: An appropriate authorization refers to a satisfactory inspection conducted in the last 3 years by a member of PIC/S or a country with a GMP MRA between said country's regulatory authority and SAHPRA NB: Please note that SAHPRA Inspectorate reserves the right to reject or approve the inspection outcome from the inspection conducted by an Authority in which a GMP MRA with SAHPRA exists.		
Documentation		1. Proof that the proposed site is appropriately authorised for the pharmaceutical form of the product concerned. 2. Applicants are to submit a resolution letter (for local sites), certificate of GMP compliance and, a manufacturing license issued within the last 3 years by SAHPRA or an authority in which a GMP MRA with SAHPRA exists (i.e., a PIC/S member state, ZAZIBONA work-sharing agreement or WHO PQ). 3. The variation application form should clearly outline the 'present' and 'proposed' finished product manufacturers as listed in section 2.5 of the application form.		

	4. SAHPRA's Biological Quality (PEM) Approval or Recommendation letter

Exception type	Addition	**SAHPRA code**	INS_A.0.1	
SAHPRA classification		Type II		
Code description		GMP Status verification of all sites listed in Medicines Register for application for a Transfer of Applicancy of HCR		
Conditions		ToHCRs do not apply for medicines that have yet to be registered. Applications will be assessed on a case–by-case basis to confirm where such changes are warranted.		
Documentation		For all the sites listed in the application form ,applicants to submit a resolution letter (for local sites), certificate of GMP compliance and a manufacturing license issued within the last 3 years by SAHPRA or an authority in which a GMP MRA with SAHPRA exists (i.e., a PIC/S member state, ZAZIBONA work-sharing agreement or WHO PQ)		

Exception type	New	**SAHPRA code**	INS_PNC01	
SAHPRA classification		Type II		
Code description		GMP Status verification of all sites listed in Medicines Register for Proprietary Name Change application of the authorised medicine		
Conditions		For Proprietary Name Change the inspectorate verify the GMP status of the manufacturing site listed in the medicines register prior to an updated registration certificate being issued. Applicants must apply for GMP Status verification to the inspectorate using an Inspectorate code simultaneously when applying for Proprietary name change.		
Documentation		For all the sites listed in the application form ,applicants to submit a resolution letter (for local sites), certificate of GMP compliance and a manufacturing license issued within the last 3 years by SAHPRA or an authority in which a GMP MRA with SAHPRA exists (i.e., a PIC/S member state, ZAZIBONA work-sharing agreement or WHO PQ)		