

A. Locally manufactured products:

1. Change in excipients (inactive) including flavor/ colour

- a. Application with required fee as per relevant SRO.
- b. Copy of registration letter and renewal status.
- c. NOC for CRF clearance.
- d. Specification of existing and proposed excipients / Flavour / Colour.
- e. Document confirming that proposed excipient / inactive is of pharmaceutical grade.
- f. Data for 06 months accelerated stability studies.
- g. Undertaking that real time stability studies would be continued till whole of shelf life & in case of OOS (out of specifications), the applicant will inform PE&R accordingly.
- h. In case of additional flavor, Application on Form 5 with full fee will be submitted.

2. Change of source of pellets

- a. Application with required fee as per relevant SRO.
- b. Copy of registration letter and renewal status.
- c. NOC for CRF clearance.
- d. Real time stability studies of pellets conducted by manufacturer as per conditions of zone IV-A as per ICH guidelines (Both real time & accelerated studies).
- e. Certificate of analysis of manufacturer
- f. GMP certificate from regulatory authority of exporting country.
- g. Undertaking that shelf life of finished product would be assigned from date of manufacturing of pellets from manufacturer.

3. Transfer of registration

i) With change in manufacturing site:

- a. Application with Form-5 and required fee as per relevant SRO.
- b. Copy of registration letter and renewal status.
- c. NOC for CRF clearance.
- d. Copy of approved section by Central Licensing Board.
- e. Copy of last inspection report.
- f. NOC from existing manufacturer / registration holder permitting for transfer of product.
- g. Statement / undertaking that applicant do not have registration of same products. If so, it has to apply for cancellation of product.
- h. Accelerated stability studies of 6 months with undertaking to conduct real time stability studies up to assigned shelf life & report if any result falls outside shelf life specifications (with proposed action).
- i. Validated method of analysis, master formula and product development data

ii) Change in name / title of manufacturer (site of manufacturing remains the same)

- a. Application on Form-5 with required fee as per relevant SRO.
- b. Copy of registration letter and renewal status.
- c. NOC for CRF clearance.
- d. Approval of new name / title from CLB.
- e. Undertaking that the formulation, API source & Specifications, manufacturing process, analytical test methods, release & shelf life specifications have not changed.

4. Change in storage conditions/shelf life

- a. Application with required fee as per relevant SRO.
- b. Copy of registration letter and renewal status.
- c. NOC for CRF clearance.
- d. Real time stability data.

5. Change in Prescribing Information (PI)

- a. Application with required fee as per relevant SRO.
- b. Copy of registration letter and renewal status.
- c. NOC for CRF clearance.
- d. Difference between existing and proposed information in tabulated form.
- e. Justification of proposed changes.
- f. Reference of prescribing information of brand leader (for me too products).
- g. Copy of approval from regulatory agency / authority from country of origin for brand leader.
- h. Copy of label outer pack in case of changes indication/ dose/ administration etc.

6. Change in primary packaging.

- a. Application with required fee as per relevant SRO.
- b. Copy of registration letter and renewal status.
- c. NOC for CRF clearance.
- d. Justification of proposed change.
- e. Accelerated stability studies of 6 months with undertaking to conduct real time stability studies up to assigned shelf life & report if any result falls outside shelf life specifications (with proposed action).
- f. Shelf life of the drug product supported with justification.

7. Change of packaging materials.

- a. Application with required fee as per relevant SRO.
- b. Copy of registration letter and renewal status.
- c. NOC for CRF clearance.
- d. Justification of proposed change.
- e. Existing and proposed packaging materials.
- f. Difference between existing and proposed information in tabulated form.
- g. Confirmation and undertaking that proposed label complies all provisions of Drugs (Labeling & Packing) Rules, 1986.
- h. An undertaking that the proposed colour scheme / label has no resemble with

already registered Products. In case of resemblance, new label will be changed immediately. Moreover, no case is pending at any forum / court of law regarding this matter.

i. Dosage, administration, indication & direction for use etc. on the label be in line with that of registration / marketing authorization.

8. Registration of drug for export purpose.

- a. Application on Form 5 with required fee as per relevant SRO.
- b. NOC for CRF clearance.
- c. Copy of approved section from CLB.
- d. Copy of last inspection report.
- e. An undertaking that applied registration is exclusively for export purpose and will not be sold in Pakistan.
- f. If formulation / product is not registered in Pakistan, then export order from importing country.

9. Change of brand name.

- a. Application with required fee as per relevant SRO (in case of similarity / resemblance with already registered drug, fee will not be required).
- b. Copy of registration letter and renewal status.
- c. NOC for CRF clearance.
- d. Justification for proposed change.
- e. Information regarding previous change of brand name since registration of drug.
- f. Details (batch number, date of manufacture, quantity and stock position) regarding last batch manufactured.
- g. An undertaking that the proposed names do not resemble with already registered brands.

In case of resemblance/similarity with already registered drug, the applicant will be liable to change immediately. Moreover, no case is pending at any forum / court of law regarding this matter.

10. Change in shape of tablet / color and size of capsule.

- a. Application with required fee as per relevant SRO.
- b. Copy of registration letter and renewal status.
- c. NOC for CRF clearance.
- d. Justification for proposed change.
- e. Undertaking that other specification of the product would remain the same.

11. Cancellation of registration of drug on firm's request.

- a. Application.
- b. Copy of registration letter and renewal status.
- c. NOC for CRF clearance.
- d. Justification
- e. List of alternatives brands available in the country.
- f. An undertaking that the no case is pending at any forum / court of law regarding this product.

12. Renewal of drugs applied after due date.

- a. Application with required fee as per relevant SRO.
- b. Copy of registration letter and last renewal status.
- c. NOC for CRF clearance.
- d. Reason for not submitting renewal in time.

13. Corrigendum for correction in registration letter.

- a. Application with required fee as per relevant SRO, if error is on part of firm.
- b. Copy of registration letter and renewal status.
- c. NOC for CRF clearance.
- d. Document in support of proposed correction.

B. Imported products:

1. Change of name of manufacturer of imported drugs

- a. Application with required fee as per relevant SRO.
- b. Copy of registration letter and last renewal status.
- c. NOC for CRF clearance.
- d. Original and legalized Certificate of Pharmaceutical Product as per WHO format for new manufacturer's name OR Original and legalized GMP certificate of new manufacturing site with free sale certificate from regulatory body of country of origin.

2. Change of manufacturing site/source

- a. Application on Form 5A with required fee as per relevant SRO.
- b. Copy of registration letter and last renewal status.
- c. NOC for CRF clearance.
- d. Original and legalized Certificate of Pharmaceutical Product as per WHO format for new manufacturer's name OR Original and legalized GMP certificate of new manufacturing site with free sale certificate from regulatory body of country of origin.
- e. Site master file of new manufacturing site.

3. Increase or decrease in shelf life of finished products

- a. Application on Form 5A with required fee as per relevant SRO.
- b. Copy of registration letter and last renewal status.
- c. NOC for CRF clearance.
- d. Justification for proposed change.
- e. Approval of regulatory body of country of origin / Original and legalized Certificate of Pharmaceutical Product as per WHO format.
- f. Stability data for Zone IV A or for respective storage condition (in case of products to be stored at 2-8 °C).

4. Transfer of registration from one importer to other importer

- a. Application on Form 5A with required fee as per relevant SRO.
- b. Copy of registration letter and last renewal status.
- c. NOC for CRF clearance.

- d. Termination letter (original) from manufacturer for previous importer.
- e. Authority letter/sole agent letter (original) from manufacturer.
- f. NOC from existing registration holder for transfer of registration.

5. Change of packaging materials.

- a. Application with required fee as per relevant SRO.
- b. Copy of registration letter and renewal status.
- c. NOC for CRF clearance.
- d. Justification of proposed change.
- e. Existing and proposed packaging materials.
- f. Difference between existing and proposed information in tabulated form.
- g. Confirmation and undertaking that proposed label complies all provisions of Drugs (Labeling & Packing) Rules, 1986.
- h. An undertaking that the proposed colour scheme / label has no resemble with already registered Products. In case of resemblance, new label will be changed immediately. Moreover, no case is pending at any forum / court of law regarding this matter.
- i. Dosage, administration, indication & direction for use etc. on the label be in line with that of registration / marketing authorization.
- j. Regulatory approval of change from country of export.

6. Change of brand name.

- a. Application with required fee as per relevant SRO (in case of similarity / resemblance with already registered drug, fee will not be required).
- b. Copy of registration letter and renewal status.
- c. NOC for CRF clearance.
- d. Justification for proposed change.
- e. Information regarding previous change of brand name since registration of drug.
- f. Details (batch number, date of manufacture, quantity and stock position) regarding last batch imported.
- g. An undertaking that the proposed names do not resemble with already registered brands. In case of resemblance/similarity with already registered drug, the applicant will be liable to change immediately. Moreover, no case is pending at any forum / court of law regarding this matter.
- h. Original and legalized Certificate of Pharmaceutical Product as per WHO format for new brand name OR Original and legalized GMP certificate of new brand name with free sale certificate from regulatory body of country of origin.