UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

الإمارات العربية المتحدة
وزارة الصحة و وقاية المجتمع

Minor Variation Guidelines for Registered Pharmaceutical Product in UAE

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I) Introduction:

This document has been developed to assist applicants in the preparation and submission of drug applications for variations to existing products to the Ministry of Health- Drug Registration Department and Quality Control Laboratory Department in UAE.

II) General Notes:

The following notes should be taken into consideration when submitting any variation application:

All days mentioned throughout this document are expressed as working days.
Application for Variation to a Marketing Authorization should always be submitted to the relevant MOH & P department.

Applicant can submit multiple applications in one entry through the online system.

A Separate Application form (signed and stamped) should be provided for each type of minor variation.

Payment of minor variation fees is for each type of minor variation.

The implementation date is 6 months from the date of the certificate.

III) Scope:

This document applies to change(s) made on medicinal products that have already received a marketing authorization from the MOH & P- UAE.

IV) Objective:

- To classify the types of variations made on registered medicinal products in UAE.
- To provide applicants with recommendations on the data required for each type of variation which may impact the safety, efficacy and quality of medicinal products.

V) Classification of Types of Variations:

Type I A: This type of variation is to be considered just a notification to the drug registration department Tell & Do (to be submitted through the online system)

A **Notification of disposition of request for variances (variation certificate)** will be issued for this type of variation

Type I B: This type of variation is to be submitted through the online system. This is a Tell; Wait & Do (wait for 10 Days) variations of Type IB that is including pricing/repricing decisions will be treated according to normal pricing procedures and communication

A **Notification of disposition of request for variances (variation certificate)** will be issued within 10 days for variations of Type I B and a pricing communication will be issued for pricing associated variations according to the normal pricing procedures.

Type II A: This type of variation is to be submitted through the online system.

This is a Tell, Wait & Do (wait for 90 days)

A **Notification of disposition of request for variances (variation certificate)** will be issued for this type of variation.

Type II B: This type of variation is to be submitted through the online system. This is a Tell, Wait & Do(wait for 60 days)

A **Notification of disposition of request for variances (variation certificate)** will be issued for this type of variation.

VI)Appendices

In order to facilitate the classification of variation or post-market changes, the appendices explicitly define the various types of changes:

Appendix 1: lists minor changes which are classified by the type of change and the conditions which frame the type of change. When the conditions are not met, the change may either classify as a major change or may make a new application as necessary.

Appendix 2: Application form

Appendix 1: List of minor changes:

1- CHANGE IN THE MARKETING AUTHORIZATION HOLDER FOR A DRUG PRODUCT:	Documents to be provided	Procedure Type
a) MAH of the finished products (change in MAH name or change of MAH address (including legal entity change)) within the same country	1,2,3,4,6(if applicable)	Type I B
b) MAH of the finished products (change in MAH name or change of MAH address(including legal entity change)) To a different country	1,2,3,4,5,6(if applicable)	Type I B
DOCUMENTS: 1. Application form signed by the new MAH 2. Notarized CPP (for any GCC country) 3. Artwork or sample from the first consignment. 4. Letter with implementation date. 5. In case the change of MAH to a different country and the MAH is the reference pricing country, then Price Certificate should be required. 6. Application form Part I to be filled signed and stamped by the new MAH along with MAH listing requirements if the new MAH is not previously recorded by the MOH DCRD. (no need to submit AF Part I in case the MAH was previously recorded by MOH&P).		

2- MANUFACTURING SITE of FINISHED PRODUCT:	Documents to be provided	Procedure Type
a) Change name or Address (same building) of manufacturing site responsible for total manufacturing process/ bulk manufacturing site/ batch release site/ primary packaging site/ secondary manufacturing site.	2,3,5,6(notarized)7, 15	Type I B
b) Change of the bulk manufacturing site.	1,2,3,4,5,6(legalized),7,8,9, 10,11,12,13,15,14,16,17,18	Type I B
c) Change in the batch release site in the same country	2,5,6(notarized),7,9,15	Type I B
d) Change in the batch release site to a different country	2,5,6,7,9,15,18 (6 &18 should be original legalized)	Type I B
e) Change in the secondary packaging site in the same country (where the release site stays the same)	2,4,5,6 (notarized),7,15	Type I B
f) Change in the secondary packaging site to a different country (where the release site stays the same)	2,4,5,6 (notarized),7,15	Type I B
g) Change in the primary packaging site in the same country	1,2,3,4,5,6(notarized),7,9,1 1,16,15,17	Type I B

h) Change in the primary packaging site to a different country.	1,2,3,4,5,6 (legalized) ,7,9,11, 2,4,5,6 (notarized),7,15,16,17	Type I B

DOCUMENTS:

1. Replacement of the relevant pages of the dossier that are affected by the variation.
2. Declaration / Justification for changing the manufacturing site.
3. Valid Manufacturing License (Proof that the proposed site is appropriately authorized for the pharmaceutical form or product concerned).
4. Copy of GMP certificate.
5. Copy of Registration certificate of the new site issued by the Drug Registration Department.
6. Certificate of a Pharmaceutical Product (CPP) stating the new manufacturing site.
7. Application form
8. A statement defining the primary steps of manufacturing process and the site at which each step takes place.
9. A declaration by the company that the manufacturing process will remain the same. In addition, the API(s), excipient(s) and their source(s), dosage form, concentration, the primary and secondary packaging, labelling, and all specifications for the product must remain the same as previously approved in the old site. A clarification of any proposed change(s) to the manufacturing of the product at the new manufacturing site should be provided and justified.
10. If the new manufacturing site uses the active substance as a starting material – A declaration by the Qualified Person (QP) or qualified key person at the site responsible for batch release that the active substance is manufactured in accordance with the detailed guidelines on good manufacturing practice for starting materials.
11. Copy of approved release and end of shelf-life specifications for the product if relevant.
12. Certificate Comparative batch analysis of drug product of at least two production batches (or one production batch and two pilot batch) form the proposed site and last three batches from the current site.
13. Relevant stability studies have been started according to the GCC stability guidelines and relevant stability parameters have been assessed in at least two pilot scale or production scale batches for at least three months.
14. A commitment letter to finalize the ongoing stabilities.
15. In case results were out of specifications, results should be submitted immediately to MOH&P with the justification and proposed actions from the company.
16. Artwork with changes if applicable.

17. For semisolid and liquid formulations in which the active substance is present in non-dissolved form, appropriate validation data including microscopic imaging of particle size distribution and morphology.

18. For solid dosage forms, data from comparative dissolution tests with demonstration of similarity of dissolution profile, performed on the last three batches from the previous site and the first three batches from the new site should be submitted.

19. A recent legalized price certificate is required if the reference pricing country is changed to another country / Price declaration if reference pricing country stays the same.

3- MANUFACTURING SITE FOR ACTIVE PHARMACEUTICAL INGREDIENT	Documents to be provided	Procedure Type
a) Change of API manufacturer	1,2,3,4,5,6,7,8, 9	Type II B
b) Addition of API manufacturer	1,2,3,4,5,6,7,8, 9	Type II B
c) Change the name of API manufacturer where the address stays the same	1,2,6 For API name change.	Type II B
d) Change in the address of the API manufacturer	1,2,6 For API address change.	Type II B
e) Deletion of API manufacturer	1,2	Type II B

DOCUMENTS:

1. Application Form.
2. Declaration letter explaining the change.
3. Acknowledgment letter from the new API manufacturer.
4. DMF open part for innovators or Certificate of Suitability /FDA approval for generic products.
5. Copy of a valid GMP certificate.
6. Accelerated stability data and Real time stability data for 6months for drug product.
7. A commitment letter to finalize the ongoing stabilities of drug product.
   In case results were out of specifications, results should be submitted immediately to MOH&P with the justification and proposed actions from the company
8. Comparative dissolution data between the old and new finished product to be submitted.

Note:
For API name change/address change that is affecting several products its advised to submit 1 file enclosing separate product applications within the single file.

4- CHANGE IN THE SOURCE OF EMPTY HARD CAPSULE	Documents to be provided	Procedure Type
Change in the source of empty hard capsule	1,2,3,4,5,6,8	Type II A

DOCUMENTS:

1. Application Form.

2. Comparative dissolution profile data with F2 between the two sources and a commitment to submit stability data once completed.
3. Certificate of Analysis of the empty hard capsule of the proposed new source.
4. Technical specifications and composition of the empty hard capsule of the new source.
5. Post marketing Stability data as per Guideline.
6. For empty hard capsule made of ruminants source, Transmitting Animal Spongiform Encephalopathy (TSE)-free certificate or Bovine Spongiform Encephalopathy (BSE)-free cert issued from competent authority of the issuing country.
7. Declaration from the manufacturer or the marketing authorization holder of the material that it is purely of vegetable, animal or synthetic origin."
8. Updated Module 3

N.B. Not applicable to change from hard capsule to soft gel.

5- DRUG PRODUCT TRADE NAME CHANGE	Documents to be provided	Procedure Type
Change in the trade name of the drug product	1,2(Notarized),3,4	Type IB

DOCUMENTS:

9. Application form.
10. CPP
11. Trade name change declaration.
12. Artwork.

6- COMPOSITION CHANGE	Documents to be provided	Procedure Type
a) Quantitative Changes in excipients	1,2,7,9,10,11,12,13,14,15, 21,22	Type II A
b) Replacement of a single excipient with comparable excipient at similar level Documents.	1,2,5,6,7,9,10,11,12,13,14,15,19,21,22	Type II A
c) Change of the coloring/flavoring agent of the product [addition, deletion or replacement of colorant(s)/flavor(s)]	1,2,5,6,15,16,18,19,20,21, 22	Type II A
d) Change in coating weight of oral dosage forms or change or weight of capsule shells	1,3,7,10,12,16, 17,21	Type II A

DOCUMENTS:

1. Application form.
2. The results of stability studies that have been carried out according to the GCC stability guidelines on the relevant stability parameters, on at least two pilot or production scale batches for 6m accelerated and real time stability.
3. A commitment letter to finalize the ongoing stabilities and to be submitted within the next renewal. In case results were out of specifications, results should be submitted immediately to MOH&P with the justification and proposed actions from the company
4. Sample of the new product, where applicable.
5. Either a TSE Certificate of Suitability for any new source of material or, where applicable, documentary evidence that the specific source of the TSE risk material has previously been assessed by a national drug regulatory authority of the ICH region and associated countries and shown to comply with the current.
6. Data to demonstrate that the new excipient does not interfere with the finished product specification test methods, if appropriate.
7. For solid dosage forms, comparative dissolution profile data of at least two pilot scale batches of the finished product in the new and old composition. For herbal products, comparative disintegration data may be acceptable.
8. For veterinary medicines intended for use in food producing, justification that the excipient does not have pharmacological activity at the dose at which it is administered to the target animal.
9. Justification of the change.
10. Supporting clinical or comparative bioavailability data or justification for not submitting a new BE study.
11. Comparative tabulated format of the current and revised product formulation Release and shelf life specifications.
12. Batch analysis data (in a comparative table) of drug product of at least 2 production (or one production batch and two pilot batches) according to currently approved and proposed product formula.
13. Specifications of the proposed excipient.
14. Process validation scheme or report appropriate to the proposed change in product formula.
15. Revised product formulation and batch manufacturing formula.
16. Revised release and end-of-shelf life specifications of the drug product.
17. Comparative tabulated format of current and proposed product and batch manufacturing formula.
18. Qualitative and quantitative information of the current and proposed coloring/flavoring agent in a comparative table.

19. Revised Leaflet/ artwork if applicable.
20. COA of finished product.
21. Updated Module 3.
22. CPP

7- CONTAINER CLOSURE SYSTEM of FINISHED PRODUCT.	Documents to be provided	Procedure Type
a) Addition or replacement or deletion of a measuring or administration device not being an integrated part of the primary packaging (Spacer devices for metered dose inhalers are excluded)	1,2,10	Type I B
b) Secondary packaging (not integrated with the finished product) Packaging Container of the finished product: • Outer Carton/Box: Change in the Dimensions, Design, Information, Code No. etc • Inner Label: Change in the Dimensions, Design, Information, Code No. etc. • Color of the closure system: Change in the color of (i.e. as color of flip- off cap, color code rings on ampoules, change of needle shield, etc • Logo: Change of the logo	1,2,9	Type I B
c) Primary (Immediate) Packaging Container of the finished product: Change in Qualitative and quantitative composition of the CCS.	1,2,3,4,5,6,7,8	Type I B
d) Primary (Immediate) Packaging Container of the finished product: Change of the closure system / Child Proof Cap, Stopper	1,2,3,4,5,6,7,8,9	Type I B

DOCUMENTS:

1. Application Form.
2. Notification Letter/ justification letter.
3. Replacement of the relevant pages of the dossier that are affected by the variation.
4. Appropriate data on the new packaging (comparative data on permeability e.g. for O2, CO2 moisture), including a confirmation that the material complies with relevant pharmacopeia requirements.
5. Proof must be provided that no interaction between the content and the packaging material occurs (e.g. no migration of components of the proposed material into the content and no loss of components of the product into the pack).
6. The results of stability studies that have been carried out according to the GCC stability guidelines on the relevant stability parameters, on at least two pilot or production scale batches for 6 months

accelerated & real time.

7. A commitment letter to finalize the ongoing stabilities.
8. In case results were out of specifications, results should be submitted immediately to MOH&P with the justification and proposed actions from the company
9. Comparative table of the current and proposed specifications, if applicable.
10. Artwork if applicable.
11. CE Mark for new administrative device if applicable.

8- STORAGE CONDITION & SHELF LIFE	Documents to be provided	Procedure Type
a) Reduction of the shelf-life of the finished product (as package for sale/after first opening/ after dilution and reconstitution)	1,2,4,6,7,8	Type II B
b) Extension of the shelf-life of the finished product (as package for sale/after first opening/ after dilution and reconstitution)	1,3,4,5, 6,7,8	Type II B
c) Change in storage conditions of the finished product or the diluted/reconstituted product	1,3,4, 5, 6,7,8	Type II B

DOCUMENTS:

1) Replacement of the relevant pages of the dossier that are affected by the variation.

2) Justification for the reduction in the shelf-life.

3) Recent *(5 years from date of completing stability*) real time stability studies (covering the entire shelf-life) conducted according to the GCC stability guidelines and relevant stability parameters have been assessed on at least three production scale batches of the finished product in the authorized packaging material and/or after first opening or reconstitution (in-use stability), as appropriate; where applicable, results of appropriate microbiological testing should be included.

4) Application form.

5) Confirmation that stability studies have been done to the currently approved protocol. The studies must show that the agreed relevant specifications are still met and no extrapolation is used.

6) Copy of approved end of shelf-life finished product specification and where applicable, specifications after dilution/reconstitution or first opening.

7) Application Form.

8) Declaration letter/ Cover letter.

9- SPECIFICATION OF FINISHED PRODUCT (Description of finished product)	Documents to be provided	Procedure Type
a) Changes of inked imprint	1,4,6,11,12,13,14,15,16,17	Type II A
b) Changes to embossing , debossing , or engraving of solid forms	1,2,4, 6,11,13,16,17	Type II A
c) Changes in scoring/break lines intended to divide into equal doses	1,2,4,5, 6,11,17	Type II A
d) Change in the shape or dimensions of the pharmaceutical form of Immediate release tablets, capsules, suppositories and pessaries	1,4,6,11,17	Type II A
e) Change in dimensions or shape without change in qualitative or quantitative composition and mean mass of tablets	1,2,3,4,5,6,11,17	Type II A
f) Specification limits are tightened	8,11,12,17	Type II A
g) Specification Limits are widened	6,8,11,12,17	Type II A
h) Deletion of test parameter and limits	6,8,11,12,16 (showing that the parameter is non-significant.(in case of non-significant parameter),17	Type II A

DOCUMENTS:

1. Replacement of the relevant pages of the dossier that are affected by the variation including a detailed drawing of the current and proposed situation.
2. Comparative dissolution data on at least one pilot batch of the current and proposed dimensions. For herbal product comparative disintegration data may be acceptable.
3. Justification for not submitting a new bioequivalence study- if applicable.
4. Samples of the finished product where applicable.
5. Data on test of content uniformity of the subdivided parts of tablets at release as conformed to compendia requirement should be submitted (only applicable for drug product with score/break-line).
6. Updated version of the specification sheet.
7. Declaration/ confirmation with no change in the qualitative and quantitative composition of the products and that specification, shelf life, storage condition will remain the same as approved.
8. Comparative table of current and proposed specification.
9. Details of any new analytical methods and validation data.
10. Batch analysis data on 2 production batches (3 production batches for biological unless otherwise justified) of the finished product for all specification parameter's.
11. Application form.

12. Qualitative and quantitative composition of the ink if purchased as mixture.
13. Certificate of analysis for 2 production/Pilot batches (in case of ink change only COA of ink / printing material (pharmaceutical grade) is required).
14. Revised drafts of the package insert and labeling incorporating the proposed variation.
15. Any ink must comply with the relevant pharmaceutical legislation.
16. Justification of the change.
17. Updated Module 3.

10- CHANGE IN THE TEST PROCEDURE OF THE DRUG PRODUCT (including replacement or addition of a test procedure)	Documents to be provided	Procedure Type
Change in the test procedure of the drug product (including replacement or addition of a test procedure)	1,2,3,4,5,6,7	Type II A

DOCUMENTS:

1. Application Form.
2. Description of the analytical methodology.
3. Appropriate verification/validation data and comparative analytical results between the currently approved and proposed test.
4. Certificate of analysis of the finished product of 2 production batches when made available.
5. Justification for the proposed change.
6. Comparative tabulated format of the currently approved and proposed release and shelf life specifications of the drug product.
7. Updated Module 3.

11- CHANGE OF BATCH SIZE	Documents to be provided	Procedure Type
a) Change of batch size of sterile drug product	1,2,3,4,5,6,8	Type II A
b) Change of batch size of non-sterile drug product	1,2,3,4,5,6,7,8	Type II A

DOCUMENTS:

1. Application form.
2. Process validation protocol and data
3. Comparative tabulated format of proposed and current batch manufacturing formula.

4. Batch analysis data (in a comparative table) of drug product on a minimum of one production batch according to currently approved and proposed batch sizes and letter of undertaking to submit batch data on the next one full production batch.
5. Stability data as per Guideline Study on Drug Product for 6 months accelerated + 6 months real time, and report if any results fall outside shelf life specifications (**for change in batch size more than or down to 10 folds compared to currently approved)** 6. Release and shelf life specifications of the drug product. 7. For oral solid dosage forms, comparative dissolution profile for at least one production batch**.** 8. Updated Module 3.

12- MINOR CHANGE OF THE MANUFACTURING PROCESS FOR DRUG PRODUCTS.	Documents to be provided	Procedure Type
a) Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product.	1,2,3,4,5,6,7,8,9,10,11,12	Type II A
b) The change relates to a biological/immunological medicinal product.	1,2,3,4,5,6,7,8,9,10,11,12	Type II A
c) Introduction of a non-standard terminal sterilization method.	1,2,3,4,5,6,7,8,9,10,11,12	Type II A
d) Increase in the overage that is used for the active substance.	1,2,3,4,5,6,7,8,9,10,11,12	Type II A
e) Minor change in the manufacturing process of an aqueous oral suspension.	1,2,3,4,5,6,7,8,9,10,11,12	Type II A
f) Minor change in the manufacturing process of an immediate release solid oral dosage form	1,2,3,4,5,6,7,8,9,10,11,12	Type II A

DOCUMENTS:

1. Variation which may have significant impact on the quality, safety or efficacy of a medicinal product, require prior approval from MOHAP UAE before implementation
2. Replacement of the relevant pages of the dossier that are affected by the variation, including a direct comparison of the present process and the new process.
3. For semi-solid and liquid products in which the active substance is present in non-dissolved form: appropriate validation of the change including microscopic imaging of particles to check for visible changes in morphology; comparative size distribution data by an appropriate method.
4. For solid dosage forms: dissolution profile data of one representative production batch and comparative data of the last three batches from the previous process; data on the next two full production batches should be available on request or reported if outside specification (with proposed action). For herbal products, comparative disintegration data may be acceptable.
5. Justification for not submitting a new bioequivalence study.
6. In case of a change to the sterilization process, validation data should be provided.
7. Copy of approved release and end of shelf-life specifications.

8. Batch analysis data (in a comparative tabulated format) on a minimum of one batch manufactured to both the currently approved and the proposed process. Batch data on the next two full production batches should be made available upon request and reported by the marketing authorization holder if outside specification (with proposed action).

9. The results of stability studies that have been carried out according to the GCC stability guidelines published on SFDA website, on the relevant stability parameters, on at least two pilot or production scale batches for at least three months.

10. A letter of commitment to finalize the stability studies and the data must be submitted immediately to the SFDA only in case of any out-of-specifications (OOS) results along with the proposed action.

11. Application Form

12. Updated Module 3.

13- PACK SIZE CHANGES	Documents to be provided	Procedure Type
a) Change of pack size **without** change in Container or closure system/ Change the presentation of the registered pack size without change in primary container or packaging material or closure system.	1,2,3,5	Type I B
b) Addition of pack size **without** change in Container or closure system.	1,2,3,5	Type I B
c) Change of pack size **with** change in Container or closure system (intact with the drug product)	1,2,3,4(notarized),6,7,8,9	Type I B
d) Addition of pack size **with** change in Container or closure system (intact with the drug product)	1,2,3,4(notarized),6,7,8,9	Type I B
e) Change the presentation of the registered pack size **with** change in primary container or packaging material or closure system.	1,2,3,5,6,7,8,9	Type I B
f) Change the presentation of the registered pack size **without** change in primary container or packaging material or closure system.	1,2,3,5,6	Type IB
g) Addition of presentation of the registered pack size with change in primary container or packaging material or closure system or device.	1,2,3,5,6,7,8,9	Type I B

DOCUMENTS:

1. Application Form.
2. Artwork.
3. Legalized Price certificate.

4. Certificate of Pharmaceutical Product.
5. Confirmation that the container closure system will stay the same as approved.
6. Replacement of the relevant pages of the dossier that are affected by the variation.
7. Appropriate data on the new packaging (comparative data on permeability e.g. for O2, CO2 moisture), including a confirmation that the material complies with relevant pharmacopeia requirements.
8. Proof must be provided that no interaction between the content and the packaging material occurs (e.g. no migration of components of the proposed material into the content and no loss of components of the product into the pack).
9. The results of stability studies that have been carried out according to the GCC stability guidelines on the relevant stability parameters, on at least two pilot or production scale batches for 6 months accelerated & real time.

14- PACK INSERT CHANGES	Documents to be provided	Procedure Type
a) Addition of new therapeutic indication.	1,2,3(legalized),4 (optional),6	Type I B
b) Modification of an approved indication	1,2,3(legalized),6	Type I B
c) Change in the range of population	1,2,3(legalized),6	Type I B
d) Deletion of therapeutic indication	1,2,3(notarized),6	Type I B
e) Deletion of contraindication, warning, precaution, & drug interaction	1,2,3(legalized),6	Type I B
f) Addition of contraindication, warning, side effects, precaution & drug interaction(Safety Updates)	1,2,3(notarized),6	Type I A
g) Rewording / Rearrangement of the pack insert	1,2,6	Type I A
h) Re-design of pack insert.	1,2,6	Type I A
i) Change in the dimension /layout of pack insert, printing color, font, shape, logo	1,2,6	Type I A
j) Change the Ref. No. and the date of revision with no actual changes to the approved information	1,2,6	Type I A
k) Changing or adding another route of administration (only for injectable solutions)	1,2,3(legalized),4 (optional),5,6	Type I B

DOCUMENTS:

1. Application Form.
2. Full set of Artwork.
3. Legalized Certificate of Pharmaceutical Product.
4. Price Certificate.
5. Summary of clinical studies/ bioavailability report
6. Comparison Tablet

15- CHANGE CONCERNING VACCINES SEROTYPE, STRAINS, ANTIGEN OR COMBINATION OF SEROTYPE, STRAINS, ANTIGEN	Documents to be provided	Procedure Type
Variations concerning the replacement or addition of a serotype, strain, antigen or combination of serotypes, strains or antigens for a veterinary vaccine against avian influenza, foot-and-mouth disease or bluetongue- (this applies to Human vaccines)	1,2,3,4,5,6,7,8,9	Type II A

DOCUMENTS:

1. Application Form.
2. Updated Artwork
3. Copy of CPP (not legalized)
4. Country of origin approval
5. Qualitative and quantitative composition
6. Change rational
7. WHO recommendation
8. Product information
9. Updated Module 3

Appendix 2: Application form

APPLICATION FOR MINOR VARIATION OF A REGISTERED PRODUCT

PRODUCT INFORMATION	
PRODUCT NAME:	
ACTIVE PHARMACEUTICAL INGREDIENT:	
DOSAGE FORM:	
STRENGTH:	
PACK SIZE:	
UAE REGISTRATION DATE & REGISTRATION NUMBER	
MARKETING AUTHORIZATION HOLDER:	
MANUFACTURING SITE:	
MANUFACTURER(S) OF ACTIVE INGREDIENT(S):	
DETAIL OF LOCAL DISTRIBUTOR:	

Description of variations (please specify descriptions according to UAE variation descriptions)	
Specify the precise present and proposed wording or specification.	
CURRENT DETAILS	**PROPOSED DETAILS**

9. Declaration

I hereby submit an application for the above product to be varied in accordance with the proposals given above. I declare that:

1. There are no other changes than those identified in this application;
2. The change(s) will not adversely affect the quality, efficacy or safety of the product;
3. The required documents as specified for the variation(s) concerned have been attached to the application.
4. All conditions as set for the variation(s) concerned are fulfilled.

NAME:	
DESIGNATION:	
EMAIL ADDRESS:	

SIGNATURE:	
DATE:	

Company stamp