Requirements for Variations to registered Herbal Products, Dietary Supplement and Medicated Cosmetic

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General requirements for all variations:

a) Letter from the MAH explaining and justifying the variation applied for.

b) Comparison table before & after change.

1. CHANGE IN PRODUCT NAME:

a) Updated & Legalized free sale certificate with the new name.

b) Commitment letter from the company stating that no change in quantity, quality, composition, or manufacturing process of the product.

c) Sample of the finished product with the new name.

d) Copy of artwork of the inner, outer label & leaflet with the new name.

2. CHANGE IN NAME OR ADDRESS OF MARKETING AUTHORIZTION HOLDER :

a) Legalized & Updated Company registration certificate, issued by the governmental competent authority.

b) Relationship letter from the manufacturer state that the relationship continues with the marketing authorization.

c) letter from the marketing authorization state that the relationship continues with the agent in Qatar.

3. CHANGE IN THE NAME OF THE MANUFACTURE SITE:

a) Legalized manufacturing license for the new name issued by the governmental competent authority.

b) Legalized (GMP) for the new name issued by the governmental competent authority

c) Legalized Relationship letter from the marketing authorization state that the relationship continues with the manufacturer

d) Commitment letter from the manufacturer that shelf life, finished product specifications, quality, and efficacy will be the same.

4. CHANGE IN SHELF LIFE:

a) Legalized approval from the health authority or updated & legalized FSC.

c) Certificate of analysis

d) Certificate of Composition

e) Stability studies long term and accelerated according to GCC guidelines (In case of extension).

f) Sample of the finished product with new shelf life.

5. CHANGE IN EXCIPIENTS:

a) Certificate of analysis

b) Certificate of Composition

c) Stability studies long term and accelerated according to according to GCC guidelines

d) Commitment letter from MAH that the finished product specification, quality,

and efficacy will be the same.

e) Commitment letter from MAH that the finished product free from prohibited substances.

f) Samples of the finished product according to PDCD lab requirements.

6. CHANGE IN PACKAGE INSERT:

a) Legalized approval from the health authority or updated & legalized FSC.

c) Old and the new package leaflet.

d) Sample of the finished product with new Package insert.

7. CHANGE OR ADDITION OF PACK SIZE:

a) Legalized approval from the health authority or updated & legalized FSC.

c) Legalized CIF Price.

d) Sample of the finished product.

8. CHANGE IN INNER AND OUTER PACK:

a) Legalized approval from the health authority or updated & legalized FSC.

c) Artwork of the new and old outer and inner pack.

d) Sample of new and old finished product.

9. CHANGE OF THE PRODUCT PRICE:

a) Legalized CIF Price.

10. CHANGE OF PRODUCT CODE NO:

a) Commitment letter from MAH that finished product specification, quality, and efficacy will be the same.

b) Commitment letter from MAH free from prohibited substances.

c) Product Artwork with new and old version

d) Sample of finished products.

e) Certificate of analysis

f) Certificate of composition