

DRUG

NATIONAL



AUTHORITY

LIST OF VARIATIONS TO BE APPLIED FOR ON NDAMIS

CATEGORY (AS IN ONLINE NDAMIS REGISTER)	TYPES OF CHANGE(S)	CLASSIFICATION
1. MAH/Licence Holder Change	Change in the name and/or corporate address of the Licence Holder	Major- 700 USD
2. API Manufacturer	a) Change in name or address of the manufacturer of an API, without change in location	Minor- zero-rated
	b) Deletion of an API manufacturing and testing site	Minor- zero-rated

	c) Addition or change of API manufacturing site with a CEP	Minor-400 USD
	d) Replacement or addition of a new manufacturer of an API	Major- 700 USD
	e) Change or addition of a manufacturing block/unit at a currently accepted API manufacturing site	Minor- zero-rated
3. FPP Manufacturer	a) Change in name or address of the manufacturer of the FPP, without change in location	Minor- zero-rated
	b) Deletion of an FPP manufacturing site	Minor- zero-rated
	c) Replacement or addition of an FPP manufacturing and testing site	Major- 700 USD
5. LTR	Change of LTR	Major- 700 USD
6. Product name	<p>Change of product name/brand name</p> <p>*Please note that addition of a product name constitutes a new application. A product can not have more than one product name</p>	Minor-400 USD
7. API retest period/shelf-life	<p>Change in the retest/shelf-life of the API involving:</p> <ul style="list-style-type: none"> • Extension 	Minor-400 USD
	<ul style="list-style-type: none"> • Reduction 	Minor- zero-rated

8. Product description/appearance	a) Change in the colouring system of the flavouring system currently used in the FPP	Minor-400 USD
	b) Change or addition of imprints, embossing or other markings, including replacement or addition of inks used for product markings and change in scoring configuration	Minor-400 USD
	c) Change in dimensions without change in qualitative or quantitative composition	Minor-400 USD
	d) Deletion of the solvent/diluent container from the pack	Minor-400 USD
9. FPP packaging (pack size, packaging material & description)- primary packaging	a) Replacement or addition of a primary packaging type	
	<ul style="list-style-type: none"> • Non sterile FPP 	Minor-400 USD
	<ul style="list-style-type: none"> • Sterile FPP 	Major- 700 USD
	b) Replacement or addition of the package size involving:	
	<ul style="list-style-type: none"> • Change in the number of units (e.g. tablets, ampoules etc) in a package 	Minor-400 USD
	<ul style="list-style-type: none"> • Change in the fill weight/fill volume of non-parenteral multidose products 	Minor-400 USD

	c) Change in the shape or dimensions of the container or closure for:	
	<ul style="list-style-type: none"> • Non-sterile FPPs 	Minor-400 USD
	<ul style="list-style-type: none"> • Sterile FPPs 	Major- 700 USD
	d) Change to an administration device that is not an integral part of the primary packaging (excluding spacer devices for metered dose inhalers) involving: <ul style="list-style-type: none"> • Addition or replacement • Deletion 	Minor-400 USD
	e) Deletion of pack size	Minor-zero-rated
10. FPP shelf-life	Change in the shelf-life of the FPP (as packaged for sale) involving: <ul style="list-style-type: none"> • Extension 	Major- 700 USD
	<ul style="list-style-type: none"> • Reduction 	Minor- 400 USD
11. FPP storage conditions	Change in the labelled storage conditions of the FPP (as packaged for sale), the product during the in-use period or the product after reconstitution or dilution	Major- 700 USD
12. Therapeutic indication(s)	Change(s) to therapeutic indication(s)	

indication or modification of an approved one

Deletion of a therapeutic indication

Minor- 400 USD