Parallel Import Licence Variation Codes

Code	Fee Type	Description	Sample Scan	Documents to be submitted
1	PLPI-Form Administrative Fee	Change in name and/or address of the holder of the Product Licence (Parallel Importer)	No	Application form
57	PLPI-Form Administrative Fee	Change in the PL number and/or name and address of the cross-referenced UK product	No	Application form
64	Leaflet/Label PLPI_Form Fee	Change in patient information leaflet and/or information for healthcare professionals	No	Application form Leaflet User test report (if required)
62	Leaflet/Label PLPI_Form Fee	Change in labels with no other change	No	Application form Label
51	PLPI-Form Administrative Fee	Change in imported MA Holder name and/or address	Yes (for non-CAP*)	Application form
48	PLPI-Form Administrative Fee	Imported MA number change	Yes	Application form Label
52	PLPI-Form Administrative Fee	Change in manufacturing name	Yes (for non-CAP*)	Application form Label Leaflet
58	PLPI_Form Standard Fee	Change in site of manufacture of imported product	Yes (for non-CAP*)	Application form Label Leaflet
42	PLPI_Form Standard Fee	Change in shelf life or storage conditions	Yes	Application form Label Leaflet
2	PLPI_Form Standard Fee	Change in PI licensed or imported product name	Yes, if imported product name	Application form Label Leaflet
40	PLPI_Form Standard Fee	Change in description/or appearance of dosage form	Yes	Application form Label (if required) Leaflet

41	PLPI_Form Standard Fee	Change in pack size of imported or marketed product	Yes (for imported)	Application form Label (marketed) Leaflet (marketed)
59	PLPI_Form Standard Fee	Change in packaging of imported product	Yes	Application form Label (if required)
60	PLPI_Form Standard Fee	Change in excipients	Yes	Application form Label (if required) Leaflet
65	PLPI_Form Standard Fee	All variations applications for PLPI licences where the cross-referenced UK product has been cancelled.	No	Application form Documents as appropriate.
50	No fee	Urgent safety update requested by MHRA	No	Application form Labels (if required) Leaflet (if required)
56	PLPI-Form Administrative Fee	Removal of product details (pack size, product name, manufacturer, ECMA number,)	No	Application form Labels (if required) Leaflet (if required)
53	PLPI-Form Administrative Fee	Change in supplier details	No	Application form
54	PLPI-Form Administrative Fee	Change in importers/distributors	No	Application form
8	PLPI_Form Standard Fee	Change in assemblers/batch release sites/storage sites	No	Application form

*CAP = Centrally Authorised Product in the EU by the European Medicines Agency

Collections of up to 50 licences are only permitted for the following variation codes:
Code 1
Code 8
Code 54
Code 53
Code 64 – The leaflets in the collection must be cross-referenced to the same UK leaflet.
Code 57 – The licences in the collection must be cross-referenced to the same UK PL number.