

PLPI submission document requirements

Table one

Information to be provided*	Document naming convention for parallel import applications to the MHRA	Requirements and additional guidance	Mandatory for submission?
1. New PLPI applications (initials)			
Covering letter	m1-0-cover-dd-mm-yyyy	<ul style="list-style-type: none"> The covering letter should include a list of the documents provided and draw attention to any special issues related to the application e.g. where the variation is submitted at the request of the MHRA Any correspondence agreeing specific fees or processing requirements with PLPI Assessment Unit should be attached to the covering letter Please see 'proof of payment' section (above) 	Yes
Application form	m1-2-form	<ul style="list-style-type: none"> All relevant parts of the application should be completed. Any sections that cannot be completed (due to the information not being available to select from drop down menus) should be entered in the Comments section of the form 	Yes
Proof of Payment Form	m1-2-5-1-proof-of-payment.pdf	<ul style="list-style-type: none"> Completed Proof of Payment form 	Yes

Labels	m1-3-1-label	<ul style="list-style-type: none"> • This is a full colour image of all components eg Carton label, bottle label, blister label, carton mock-ups and Braille labels • All components should be combined into one file even if a number of different product names and pack sizes are to be used (see guidance documentation) • The licence holder number should be present 	Yes
Leaflet	m1-3-1-leaflet	<ul style="list-style-type: none"> • A leaflet is a full colour image of a document which fulfils the requirements of article 59 of the Directive as amended • All leaflets should be combined into one file even if a number of different product names are to be used (see guidance documentation) • The licence holder number should be present 	Yes
Suppliers	m1-2-suppliers	<ul style="list-style-type: none"> • A complete lists of suppliers should be provided 	<p>Yes - unless an assurance of appropriate sourcing signed by a company director has been submitted and acknowledged.</p> <p>It is sufficient to provide this information on the application form only when there are five companies or less.</p> <p>Where the number of Suppliers exceeds five companies then a separate list must be provided</p>

Company Function List	m1-2-company-function-list	<ul style="list-style-type: none"> This list should include assemblers, importers, storage and batch release sites 	<p>Yes</p> <p>It is sufficient to provide this information on the application form only when there are five companies or less.</p> <p>Where the number of companies listed exceeds five then a separate list must be provided</p>
2. Responses to requests for information (RFIS) sent by the MHRA (PLPI unit)			
Covering letter	m1-0-cover-dd-mm-yyyy	<ul style="list-style-type: none"> This should be dated appropriately with date of submission The covering letter should include a list of the documents provided and draw attention to any special issues related to the application eg where the variation is submitted at the request of the MHRA Any correspondence agreeing specific fees or processing requirements with PLPI Assessment Unit should be attached to the covering letter Please see 'proof of payment' section above 	Yes
Application form	m1-2-form-dd-mm-yyyy	<ul style="list-style-type: none"> The complete form must be supplied, and not just amended pages All relevant parts of the application should be completed. 	*If applicable

Labels	m1-3-1-label-dd-mm-yyyy	<ul style="list-style-type: none"> • This is a full colour image of all components eg Carton label, bottle label, blister label, carton mock-ups and Braille labels • All components should be combined into one file even if a number of different product names and pack sizes are to be used (see guidance documentation) • The licence holder number should be present 	*If applicable
Leaflet	m1-3-1-leaflet-dd-mm-yyyy	<ul style="list-style-type: none"> • A leaflet is a full colour image of a document which fulfils the requirements of article 59 of the Directive as amended • All leaflets should be combined into one file even if a number of different product names are to be used • The licence holder number should be present 	*If applicable
Suppliers	m1-2-suppliers-dd-mm-yyyy	<ul style="list-style-type: none"> • Indicate clearly how the list has been amended ie deletions or additions 	<p>*If applicable</p> <p>It is sufficient to provide this information on the application form only when there are five companies or less.</p> <p>Where the number of Suppliers exceeds five companies then a separate list must be provided</p>

Company Function List	m1-2-company-function-list-dd-mm-yyyy	<ul style="list-style-type: none"> This list should include assemblers, importers, storage and batch release sites Amendments to the list must be clearly indicated 	<p>*If applicable</p> <p>It is sufficient to provide this information on the application form only when there are five companies or less.</p> <p>Where the number of companies listed exceeds five then a separate list must be provided</p>
<p>3. PLPI variation applications (see table two for the specific fees and document requirements for each variation code)</p>			
Covering letter	m1-0-cover-dd-mm-yyyy	<ul style="list-style-type: none"> This should be dated appropriately with date of submission The covering letter should include a list of the documents provided and draw attention to any special issues related to the application e.g. where the variation is submitted at the request of the MHRA Any correspondence agreeing specific fees or processing requirements with PLPI Assessment Unit should be attached to the covering letter Please see 'proof of payment' section (above) 	Yes
Proof of Payment Form	m1-2-5-1-proof-of-payment.pdf	<ul style="list-style-type: none"> Completed Proof of Payment form 	Yes

Labels	m1-3-1-label	<ul style="list-style-type: none"> • This is a full colour image of all components eg Carton label, bottle label, blister label, carton mock-ups and Braille labels • All components should be combined into one file even if a number of different product names and pack sizes are to be used (see guidance documentation) • The licence holder number should be present 	**If applicable
Leaflet	m1-3-1-leaflet	<ul style="list-style-type: none"> • A leaflet is a full colour image of a document which fulfils the requirements of article 59 of the Directive as amended • All leaflets should be combined into one file even if a number of different product names are to be used (see guidance documentation) • The licence holder number should be present 	**If applicable
Suppliers	m1-2-suppliers	<ul style="list-style-type: none"> • Indicate clearly how the list has been amended ie deletions or additions 	<p>**If applicable</p> <p>It is sufficient to provide this information on the application form only when there are five companies or less.</p> <p>Where the number of Suppliers exceeds five companies then a separate list must be provided</p>

Company Function List	m1-2-company-function-list	<ul style="list-style-type: none"> This list should include assemblers, importers, storage and batch release sites 	<p>**If applicable</p> <p>It is sufficient to provide this information on the application form only when there are five companies or less.</p> <p>Where the number of companies listed exceeds five then a separate list must be provided</p>
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4. PLPI renewals

Covering letter	m1-0-cover-dd-mm-yyyy	<ul style="list-style-type: none"> This should be dated appropriately with date of submission The covering letter should include a list of the documents provided and draw attention to any special issues related to the application e.g. where the variation is submitted at the request of the MHRA Any correspondence agreeing specific fees or processing requirements with PLPI Assessment Unit should be attached to the covering letter Please see 'proof of payment' section 	Yes
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Proof of Payment Form	m1-2-form-dd-mm-yyyy	<ul style="list-style-type: none"> All relevant parts of the application should be completed Any sections that cannot be completed (due to the information not being available) should be entered in the Comments section of the form 	Yes
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4. PLPI Change of ownerships (COAs)

Covering letter	m1-0-cover-dd-mm-yyyy	<ul style="list-style-type: none"> • This should be dated appropriately with date of submission • The covering letter should include a list of the documents provided and draw attention to any special issues related to the application e.g. where the variation is submitted at the request of the MHRA • Any correspondence agreeing specific fees or processing requirements with PLPI Assessment Unit should be attached to the covering letter • Confirmation that there are no pending submissions on the existing licence • Please see 'proof of payment' section 	Yes
Application form	m1-2-form-dd-mm-yyyy	<ul style="list-style-type: none"> • All relevant parts of the application should be completed • Any sections that cannot be completed (due to the information not being available) should be entered in the Comments section of the form 	Yes
Proof of Payment Form	m1-2-5-1-proof-of-payment.pdf	<ul style="list-style-type: none"> • Completed Proof of Payment form 	Yes

Labels	m1-3-1-label	<ul style="list-style-type: none"> • This is a full colour image of all components eg Carton label, bottle label, blister label, carton mock-ups and Braille labels • All components should be combined into one file even if a number of different product names and pack sizes are to be used (see guidance documentation) • The details should be identical to the last approved labels for the source licence except for the new licence holder details and new PI licence number 	Yes
Leaflet	m1-3-1-leaflet	<ul style="list-style-type: none"> • A leaflet is a full colour image of a document which fulfils the requirements of article 59 of the Directive as amended • All leaflets should be combined into one file even if a number of different product names are to be used (see guidance documentation) • The details should be identical to the last approved leaflet for the source licence except for the new licence holder details and new PI licence number 	Yes
Letter regarding COA	M1-0-cover-COA	<ul style="list-style-type: none"> • Letters from companies involved confirming the transfer of licence(s) from one company to another • The cancellation date for the existing licence should be clearly stated on the letter 	Yes

* The supporting documents to be provided will be dependent on the Request for Further Information.

** The supporting documents required for a variation submission will be dependent on the type of variation being submitted – please see ii) below.

Table two

Fee type	Fee (£)	Variation type	Variation reason	Var. code	Documents required
No fee liability	0	Imported MA number change.	To update / add *country* MA number to 'xxxxxx'.	48	m1-0-cover-dd-mm-yyyy m1-2-5-1-proof-of-payment.pdf m1-2-form m1-3-1-label
		Urgent amendments to label or PIL for safety reasons at MHRA request.	As appropriate	49	m1-0-cover-dd-mm-yyyy m1-2-5-1-proof-of-payment.pdf m1-2-form m1-3-1-label or m1-3-1-leaflet
VAR PLPI admin national	0	Change in name and / or address of the Holder of the Product Licence (Parallel Import).	To update the name and / or address of the PL Holder from 'yyyyyy' to 'xxxxxx'.	1	m1-0-cover-dd-mm-yyyy m1-2-5-1-proof-of-payment.pdf m1-2-form (including assurance of change on all labels and leaflets)
		Change in imported MA holder name and / or address.	To update the name and address of the *country* MA Holder from 'yyyyyy' to 'xxxxxx'.	51	m1-0-cover-dd-mm-yyyy m1-2-5-1-proof-of-payment.pdf m1-2-form
		Change in name of manufacturer but not site or address.	To update the name of the manufacturer from 'yyyyyy' to 'xxxxxx' with consequential changes to the labels and leaflet.	52	m1-0-cover-dd-mm-yyyy m1-2-5-1-proof-of-payment.pdf m1-2-form m1-3-1-label m1-3-1-leaflet
		Change in suppliers details.	To change the list of suppliers of the *country* product	53	m1-0-cover-dd-mm-yyyy m1-2-5-1-proof-of-payment.pdf

					m1-2-form Suppliers List (dated appropriately)
		Addition of importers/storage sites.	To change the list of importers/storage sites of the *country* product adding *company*	54	m1-0-cover-dd-mm-yyyy m1-2-5-1-proof-of-payment.pdf m1-2-form Amended importers / storage sites dated appropriately
		Deletion of sites of importation, supply, manufacture, assembly, batch release, storage, distribution.	To change the list of importers/storage sites of the *country* product deleting *company*	55	m1-0-cover-dd-mm-yyyy m1-2-5-1-proof-of-payment.pdf m1-2-form Amended lists (storage, assembly, batch release, supply, manufacture, distribution) indicating clearly sites for deletion dated appropriately
		Removal of product details (eg pack size, product name).	To delete the product name 'yyyyy' with consequential changes to the labels and leaflet.	56	m1-0-cover-dd-mm-yyyy m1-2-5-1-proof-of-payment.pdf m1-2-form m1-3-1-label m1-3-1-leaflet
		Change in PL number and / or name and address of the cross referenced UK product.	To change the cross-referenced UK MA from PL 00001/0001 to PL 00002/0002 held by *company name and address*	57	m1-0-cover-dd-mm-yyyy m1-2-5-1-proof-of-payment.pdf m1-2-form

Table three

Fee type	Fee (£)	Variation type	Variation reason+-	Var. code	Documents required
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VAR PLPI stand national	397	Site of manufacture of imported product	To change the address of the manufacturer of the *country* product to *company name and address* with consequential changes to the labelling and leaflet (to the version dated *date*).	58	m1-0-cover-dd-mm-yyyy m1-2-5-1-proof-of-payment.pdf m1-2-form m1-3-1-label m1-3-1-leaflet
		Change in assemblers / batch release sites/ storage sites.	To change the list of importers/storage sites of the *country* product	8	m1-0-cover-dd-mm-yyyy m1-2-5-1-proof-of-payment.pdf m1-2-form Amended lists (storage, assembly, batch release, supply, manufacture, distribution) indicating clearly the changes and dated appropriately.
		Change in product name	To change/add the product name to 'yyyyyyy' with consequential changes to the labels and leaflet.	2	m1-0-cover-dd-mm-yyyy m1-2-5-1-proof-of-payment.pdf m1-2-form m1-3-1-label and m1-3-1-leaflet
		Change in description/or appearance of dosage form	To change the description of imported product to 'yellow, round, film coated tablet with a score line on one face and plain on the other' with consequential changes to the leaflet.	40	m1-0-cover-dd-mm-yyyy m1-2-5-1-proof-of-payment.pdf m1-2-form m1-3-1-leaflet
		Change in packaging	To change the packaging from a product packed in a bottle of 100 tablets to a blister packed product of 28 (2x14) tablets with consequential changes to the labels and leaflet.	59	m1-0-cover-dd-mm-yyyy m1-2-5-1-proof-of-payment.pdf m1-2-form m1-3-1-label and m1-3-1-leaflet

		Change in pack size	To change the pack size to 28 (2x14) with consequential changes to the labels and leaflet.	41	m1-0-cover-dd-mm-yyyy m1-2-5-1-proof-of-payment.pdf m1-2-form m1-3-1-label and m1-3-1-leaflet
		Change to Excipients	To update the list of excipients to include '*excipient*' with consequential changes to the leaflet.	60	m1-0-cover-dd-mm-yyyy m1-2-5-1-proof-of-payment.pdf m1-2-form m1-3-1-label (if excipients of known effect) and m1-3-1-leaflet
		Change in shelf life or storage conditions	To change the storage precautions to 'Do not store above 25oC' with consequential changes to the labels and leaflet.	42	m1-0-cover-dd-mm-yyyy m1-2-5-1-proof-of-payment.pdf m1-2-form m1-3-1-label and m1-3-1-leaflet
PLPI LAB/LEA STD national	364	Change in labels with no other change.	To add Braille to over labels and cartons.	62	m1-0-cover-dd-mm-yyyy m1-2-5-1-proof-of-payment.pdf m1-2-form m1-3-1-label
		Change in information leaflet.	To amend 'XXXX' and 'YYYY' sections in line with the current UK PIL dated 'dd/mm/yyyy'. PLPI revision date 'dd/mm/yyyy'	64	m1-0-cover-dd-mm-yyyy m1-2-5-1-proof-of-payment.pdf m1-2-form m1-3-1-leaflet