Guidance on Converting Parallel Distribution Notices (PDNs) to UK Parallel Import Licences (PILs) in a no-deal Brexit

The process to convert Parallel Distribution Notices (PDNs) into Parallel Import Licences (PILs) if there is a no-deal Brexit.

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Contents

This guidance will apply from exit day in line with the Human Medicines Regulations (Amendment etc.) (EU Exit) Regulations 2019.

If there is a no-deal Brexit, the UK will need to put in place arrangements for the continued authorisation of medicinal products.

This guidance provides detailed description of the process we have put in place to convert your Parallel Distribution Notices (PDNs) into Parallel Import Licences (PILs) in the event of a no-deal Brexit.

Outline of the process for converting PDNs to PILs

PDN holders are given the opportunity to opt-in to the conversion process for all or some of their PDNs by notifying the MHRA in writing as described below. This process requires minimal information from PDN holders.

If you choose not to opt-in, following the day the UK leaves the EU your product(s) will no longer be licensed in the UK and you will no longer be able to place them on the market in the UK.

MHRA will allocate Product Licence (PL) numbers to PDNs based on the existing practice for determining how many separate national licences are needed across a product range. All pack sizes will be covered by a single PL number.

PILs will be valid for a single source country and a separate PIL will be issued for each source country you request.

There is no fee associated with the conversion from a PDN to a UK PIL.

Detailed description of the process for converting PDNs to PILs

Actions to take if you are a PIL holder

PILs are being issued as a replacement for PDNs (which will no longer be valid in the UK) and will be issued to the holder of the PDN.

The PDN holder will need to have a company number allocated by MHRA as this forms part of the PL number which will be allocated to each PIL.

If you do not already have a MHRA-allocated company number please contact plpi@mhra.gov.uk as soon as possible for instructions on how to apply for a number.
PIL holders will need to be established in the UK from exit day until the end of the implementation period. If you are a PDN holder not established in the UK, but you have an associated company established in the UK which you would like to be the holder of your PILs, please contact MHRA as soon as possible to make this arrangement.
If you do not have an associated, UK-based company you will need to establish a company in the UK beginning on the day the UK leaves the EU until the end of the implementation period. Please contact MHRA plpi@mhra.gov.uk as soon as this company has been allocated a number by MHRA and your PILs will be transferred to the new company for no fee.

How to opt in

PDN holders have been provided with a list of PDNs understood to be valid on 31 December 2018. This list will be updated before the UK leaves the EU.

Check this list very carefully and please contact MHRA plpi@mhra.gov.uk of any discrepancy.

Some PDNs refer to EU licence numbers which are not listed in the current product information available on the EMA website. These presentations may no longer be valid and PILs will not be issued for them unless you specifically request one.

The list includes a column for the source countries you want to use for each product. A separate PIL will be issued for each source country you request. If you do not want your PDN for any product converted to a PIL, please enter “none” in this column.

Return the completed list as soon as possible to plpi@mhra.gov.uk.

You must return the list within 3 weeks of the day the UK leaves the EU if you wish to take part in the conversion process. It will not be possible to

convert further PDNs after the end of this 3-week period and a fresh application for a parallel import licence would be necessary, with the associated fee payable.

How to request further information from companies involved in repacking

PILs require some additional information about the companies involved in the repacking process, including the supplier from whom the product is obtained and the companies involved in importing, repacking, batch release, storing and distributing the product.

Supplier information should be addressed by completing a “supplier commitment”, signed by a company director. This is a commitment to confirm validity of authorisations and to record details of the source of each batch of product repacked. For details of the wording required, please contact plpi@mhra.gov.uk. This commitment must be returned before any PIL numbers can be issued and no later than 4 weeks after the UK leaves the EU.
Companies involved in repacking are best managed using a “Company Functions List”. This can be updated at any time by submitting an updated list to plpi.admin@mhra.gov.uk. The latest list will be applied when a new PIL is granted.
Please contact plpi@mhra.gov.uk for a template and example document. This information must be returned before any PIL numbers can be issued and no later than 4 weeks after the UK leaves the EU.

Issue of PL numbers

As soon as possible after receipt of the list of PILs you require, MHRA will return an updated list which includes a PL number allocated to each product/source country requested.

After the UK leaves the EU

Immediately after Brexit you may continue to repack and release those products for which you have requested a PIL using labels and leaflets consistent with the latest annex on the EMA/EC website and carrying the EU licence number.

Products for which you have not requested a PIL may not be released after the day the UK leaves the EU.

Once you have received your list of PIL numbers you should update the labels and leaflet to use these numbers as soon as practicable.

You should continue to monitor the EMA/EC website and update the labels and leaflet used in your released product to remain consistent with the latest annex on the EMA/EC website.

Receipt of PILs

We expect that it will take some months to issue all of the PILs required. They are likely to be produced on a ‘by product’ rather than a ‘by importer’ basis.

The PILs produced will use a substitute UK reference MA to allow cases to be created in our licence management system before the relevant UK MA for the reference product has been issued. A change of UK reference product variation will be applied to each PIL by MHRA at no fee at a later date.

The PILs produced as part of this process will use the EMA/EC annexes for the label and leaflet documents. No “user test” of the patient leaflet will be required.

PIL maintenance

Once a PIL for a converted product is issued the established Parallel Import variation process applies. Variations should be submitted and approved before an affected product is released, unless the change falls

within the Tell-and-Do scheme. Scans of samples should be submitted when required.

The first variation affecting labels and/or leaflets must be accompanied by a mock-up of the respective document(s). In the case of labels this must begin with the label summary sheet. Please contact plpi@mhra.gov.uk for a template.
This guidance will apply from exit day in line with the Human Medicines Regulations (Amendment etc.) (EU Exit) Regulations 2019.

Further information

Please contact plpi@mhra.gov.uk if you have any questions about this process.