Parallel Import Applications – Guidance concerning requests for further information (RFIs)

Background

The current service level agreement between the Agency and the PLPI companies is 120 'clock on' days. A review of the current process has revealed that the average number of RFI cycles per application is quite high and has a negative impact on assessment times. The Agency has therefore been looking at ways to improve and speed up current application process.

A major cause of delay arises because applications for parallel import licences are often submitted without adequate or complete information and documents. Delays also occur in situations where the Agency considers that changes need to be made, for example to packaging and leaflets.

Hitherto, in those circumstances the Agency has engaged in extensive and time consuming dialogue and correspondence with the applicant in order to obtain the information and agree the changes. The Agency has decided that it will no longer keep an application in process indefinitely pending receipt of the required information or reaching agreement in relation to the changes to packaging and leaflets.

From the 7th of January 2008, the Agency will correspond with the applicant twice, to explain the information which is missing or the changes which are required. If after this the applicant has not sent the information or made the required changes within the time specified in the correspondence the Agency will make a decision whether or not to grant the parallel import licence.

A third and final letter will be sent before the application is determined as refused.

Exemptions to this rule will be allowed in exceptional circumstances, for example when the leaflet is undergoing user testing. These exemptions will be decided on a case by case basis.

This document explains the steps in the application process and sets out the time scales in which the Agency aims to complete each step. It also gives guidance to applicants as to how to avoid requests for more information and the time they will have to reply to the Agency's requests for more information or changes. It is hoped that this will:

- enable consistency of approach.
- ensure the assessment procedure runs efficiently, balancing the needs of applicants to adequately address issues with the requirements for assessors to assess applications in an efficient and timely manner
- enable applicants to have sufficient time to respond to issues raised during the assessment process.

1) Applications - documents and information required.

So that it can be processed without delay an application for a parallel import licence should be accompanied by the following particulars and documents. These documents

are required so that the Agency can ascertain whether the product is one to which the parallel import scheme applies and whether it may be safely marketed in the UK:

- an accurately completed MLA form indicating the appropriate UK cross-reference product on which the application is based
- the relevant complete sample with the foreign leaflet intact
- mock ups of all proposed labelling and patient information leaflet (PIL) in English
- the appropriate fee should be paid immediately on receipt of the invoice

Applications to vary a licence must in addition to the above, state the specific reason for the variation clearly and accurately on the relevant MLA form.

2) The Assessment Process

Following successful validation (that is to say the checking by the Agency that all required documents have been submitted and the inputting of all relevant information on to the database), the Agency will request the ECMA report containing the necessary product details as authorised in the exporting Member State from the competent authority who granted the MA for the product. Once the Agency receives this the application is then 'ready for assessment', and is placed on the allocation list.

The application is subsequently allocated to an assessor and the assessment process commences.

Initial assessment

If, after an initial assessment, it is clear that there are major deficiencies in the quality, safety or efficacy of the product, or questions regarding the suitability of the product to be imported under the parallel import scheme, a report will be completed and the application will be considered for a refusal decision unless further information is requested by the Unit Manager as appropriate.

For all other applications, the following is envisaged:

Net Calendar days

Assessment Step I

Day 0	Joint assessment report (pharmaceutical & scientific) to be completed. Application processed as described at Day 50 if no information or changes are required otherwise the1st request for further information (RFI) or for changes to be made is sent to the applicant. The company has up to 30 days to respond to the RFI. (Clock off)

Assessment Step II

Day 1	1st response received and assessors have up to 20 days to assess the response (Clock on)
Day 20	Application dealt with as at Day 50 if applicant has fully complied with initial requests otherwise a 2nd RFI or a reminder if no response has been received is sent.

	Company has up to 20 days to respond to 2nd RFI. (Clock off)
Day 21	2nd response received and assessors have up to 20 days to assess the response (Clock on)

Final Step

Day 40	If 2nd response is not satisfactory or no response has been received from the applicant, assessors to send a letter notifying the company that the application will be refused if an appropriate response is not received within 20 days. (Clock off), otherwise proceed as for Day 50
Day 41	3rd response is received. Assessors have 10 days to assess 3rd response. (Clock on)
Day 50	If the response accurately addresses all requested amendments, the application is signed off and forwarded to the administrative team for determination. The administrative team has up to 10 days to check the application and prepare the necessary documents prior to granting the licence. If the response is incomplete or inadequate, the application is determined as 'refused'.
Day 60	Application is granted or refused. Procedure closed on Day 60 at the latest.

To ensure that this time table is achieved, it is imperative that once the initial assessment has been completed that no data or changes are introduced. These include but are not limited to:

- new samples with additional ECMA numbers
- new pack sizes
- introduction of new product names
- introduction of new packaging

Companies are advised to add these or similar amendments to the granted licence via the relevant variation applications.