The European Agency for the Evaluation of Medicinal Products
Post-authorisation Evaluation of Medicines for Human Use

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PROCEDURE FOR NOTIFICATIONS OF PARALLEL DISTRIBUTION OF CENTRALLY AUTHORISED MEDICINAL PRODUCTS

This procedure is intended to provide guidance and assist parallel distributors to fulfil their obligations, without prejudice to the interpretation of Community Directives and Regulations by the European Commission and/or European Court of Justice.

Background

Reference is made to the "Commission Communication on the Community Marketing Authorisation Procedures for medicinal products" (O.J. C229/4 of 22.7.98), in which the EMEA is the Authority designated to check compliance of a product distributed in parallel with the terms of the Community Marketing Authorisation for the concerned centrally authorised medicinal product.

A Community Marketing Authorisation is valid throughout the European Union and a centrally authorised medicinal product is therefore by definition identical in all Member States. As a consequence, products put on the market of one Member State can be marketed in any other part of the Community by a distributor ("parallel distributor") independent of the Marketing Authorisation Holder. The only changes parallel distributors may introduce to the packaging of a centrally authorised medicinal product are those which are strictly necessary to market the product in the Member State of destination [use of different language version(s) of product information; change in package size in exceptional cases and only where the proposed size falls within the scope of the Community marketing authorisation].

Parallel Distributors are reminded that, according to the current case-law of the Court of Justice of the European Communities, the trade mark owner must be given advance notice by the parallel distributor that the repackaged product is to be put on sale.

The EMEA will operate the following procedure, which will enter into force on 20 November 1998.

1. Information to be provided to the EMEA

At least 3 months prior to commencing distribution of a specific product, the parallel distributor sends the complete information (see notification form in attachment) to the EMEA - Human or Veterinary Medicines Evaluation Unit - Parallel Distribution.

Depending on the nature of changes the parallel distributor intends to introduce, the following information shall be provided, as outlined in the form:

1.1 Where no repackaging[1] is carried out

(a) Name or business name of the parallel distributor.
(b) Name of the medicinal product concerned and marketing authorisation number in the Community Register of Medicinal Products.
(c) Names of Member State(s) of origin (= where the product is sourced) and Member State(s) of destination (= where the product will be distributed).
(d) Mock-up[2] of the medicinal product of the Member State of destination. Outer and/or inner packaging and package leaflet are to be provided (in 2 copies, preferably in colour).
A specimen[3] of the medicinal product will have to be provided before issuance of the EMEA notice (see point 2).
(e) Electronic version of the texts for outer/inner packaging and package leaflet (Word 6/8).
(f) Copy of the Wholesale Distribution Authorisation within the meaning of article 3(1) of Council Directive 92/25/EEC or article 50a(1) of Council Directive 81/851/EEC.

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(g) Details of person to contact in case of quality problems and defective batches: name, full address, 24-hour contact number, fax and E-mail address.
(h) Certification that the original condition of the medicinal product has not been directly or indirectly affected.
(i) Payment to the EMEA of an administrative charge of 3,480 EURO for each notification[4]. This charge will cover all "notifications of a change" after obtaining the EMEA notice. Attach proof of payment.

1.2 Where repackaging is carried out

The following additional information shall be provided:
(j) Copy of the Manufacturing Authorisation within the meaning of article 16(1) of Council Directive 75/319/EEC or article 24(1) of Council Directive 81/851/EEC for the site where repackaging is carried out.
(k) Detailed justification that the repackaging and/or change of pack-size is necessary to distribute the product in the Member State of destination.
(l) In case of changes to the pack-size: detailed justification for this change and confirmation that the proposed pack-size falls within the scope of the Community marketing authorisation.

2. EMEA validation, check and notice

Validation
Upon receipt of the notification, the EMEA will check its completeness within 5 working days and contact the applicant if any information is missing or incorrect.

Check
The EMEA will check the conformity of the proposed labelling and package leaflet with the text of the Commission Decision granting or amending the marketing authorisation (labelling, package leaflet, packaging and pack sizes) within 30 working days from receipt of the validated information and will notify the parallel distributor of any objection, stating in details the reasons for such objection. The check will be suspended until receipt of the amended information.

Notice
When there are no objections or when objections have been completely addressed in those 30 working days, the EMEA will send a notice to the parallel distributor, the Member State of destination and the Marketing Authorisation Holder of the medicinal product, indicating that the regulatory check has been completed.

The EMEA will inform the European Commission (DGIII/E/3) on a monthly basis on the status of parallel distribution notices issued by the EMEA.

3. Post-Notice obligations – "Notification of a change"

Parallel distributors must ensure that the product information remains in conformity with the latest Community Decision granting or amending the marketing authorisation.

The Marketing Authorisation Holder may make amendments to the product information as a result of maintenance operations (e.g. variations, urgent safety restrictions).
Therefore, parallel distributors must regularly check whether amendments to the latest Commission Decision relating to the medicinal product have been made.
These amendments are reflected in the European Public Assessment Reports (EPARs). EPARs will be made available in all EU official languages on the EMEA Website http://www.emea.eu.int.
Meanwhile, annexes to Commission Decisions can be obtained upon request from the EMEA.

Where amendments affecting product information (labelling and leaflet) are identified or where any other information previously provided to the EMEA changes (e.g. change in repackager), the parallel distributor shall send a completed Notification of a change (see form in attachment) to the EMEA, without delay.

Within 30 working days from receipt of the complete information, the EMEA will check the amended information following the procedure described under point 2 above. Once the regulatory check has been satisfactorily completed, the EMEA will inform the Parallel Distributor accordingly.

If parallel distributors do not amend their product information in line with the updated Commission decision, the EMEA will inform the parallel distributor, the Marketing Authorisation Holder, the European Commission (DGIII/E/3) and the Member State of destination without delay of this non-compliance.

[1] The ECJ has defined "repackaging" as including operations such as "removal of blister packs from the original external packaging and their insertion into new external packaging" or "addition to the packaging of new user instructions or information or the fixing of self-stick labels" (ECJ, 11 July 1996, MPA Pharma GmbH vs Rhone Poulenc Pharma GmbH (C-232/94) and BMS vs Paranova A/S (C-427/93, C-429/93,C-436/93) and joined cases C-71/94, C-72/94, C-73/94)).

[2] A "Mock-up" is a copy of the flat artwork design in full colour, providing a replica of both the outer and immediate packaging and of the labelling text of the medicinal product. It is generally referred to as a "paper copy" or "computer generated version".

[3] A "Specimen" is a sample of the (repackaged) sales presentation of the medicinal product.

[4] Council Regulation (EC) No 494/2003 on Fees payable to the European Agency for the Evaluation of Medicinal Products, as amended.