



European Medicines Agency  
*Post-authorisation Evaluation of Medicines for Human Use*

London, 06 July 2006  
EMA/Ho/2368/Rev 3

<p align="center"><b>EMA POST-AUTHORISATION GUIDANCE ON PARALLEL DISTRIBUTION</b></p>
---

<b>RELEASE FOR CONSULTATION (6 weeks)</b>	February 2004  (Until 13 April 2004)
<b>IMPLEMENTATION OF COMMENTS</b>	April 2004
<b>RELEASE OF FINAL DOCUMENT</b>	19 May 2004

Updates and amendments introduced in this revision are identified respectively as “UPDATE” and “NEW” throughout the document.

## EMEA POST-AUTHORISATION GUIDANCE – PARALLEL DISTRIBUTION (PD)

This guidance document addresses a number of questions, which parallel distributors/marketing authorisation holders may have on PD notification procedures. It also provides an overview of the EMEA position on issues.

This guidance is intended to give clarifications on the current handling of PD notifications in accordance with the “Procedure for notifications of parallel distribution of Centrally authorised Products” (EMEA/H/30313/98 Rev 2”).

Proposed procedural changes are identified as “NEW” throughout the document.

This document will be updated regularly to reflect new developments/revisions resulting from accumulated experience in this field.

This guidance information and pre-notification dialogue between a parallel distributor and the EMEA should enable the parallel distributor to submit notifications, which are in conformity with the legal and regulatory requirements and which can be validated and processed speedily.

To obtain the information on a certain topic, simply **click** on the **highlighted key word**. We trust that the information, linked to the key word, answers most of your queries. However, in case of doubt, we strongly encourage a parallel distributor in such cases to contact the PD Secretariat.

### Update:

- For any issues related to a PD notification for a specific product or request for latest texts of a Commission Decision: please send your queries/requests to [paralleldistribution@emea.eu.int](mailto:paralleldistribution@emea.eu.int) or contact **Popi Pappou (+ 44 207 523 7073)**, **Jolanta Thatcher (+44 207 418 8591)** or **Silvia Day (+44 207 523 7169)** from 2.00 to 4.00 pm.
- For more detailed queries on regulatory/legal and procedural matters related to PD notifications, you will be directed to the Scientific Administrator responsible for Parallel Distribution in the Regulatory Affairs and Organisational support Sector.

Please click [here](#) to enter into the list of questions.

Note:

- Please note that this document has been produced for guidance only and should be read **in conjunction** with relevant Community legislation and the Commission Communication on the relevant Community marketing authorisation procedures for medicinal products (98/C 229/03) OJ C 229 of 22 July 1998.

## Parallel distribution notifications

1. Is it possible to [distribute](#) a centrally authorised medicinal product from one EU member state into another member state of the Community?
2. Is the EMEA PD notification procedure [mandatory](#)?
3. How shall I [present](#) my initial PD notification?
4. How and to whom shall I [submit](#) my initial PD notification?
5. [When](#) shall I submit my initial PD notification?
6. How shall my initial PD notification be handled ([timetable](#))?
7. Where can I obtain the [latest texts for labelling and package leaflet](#) for a given centrally authorised product?
8. Is there any [deviation](#) allowed to the texts of the Commission Decision for a certain product?
9. Can I interchange [multiple licenses](#) in the context of parallel distribution?
10. Can I propose a [bundle-pack](#) of existing presentations in the context of parallel distribution?
11. How many [PD notifications](#) shall I submit for a given medicinal product?
12. What [fee](#) do I have to pay for an initial PD notification?
13. Do I need to submit [colour copies and printed package leaflets](#) with my initial PD notification?
14. Do I need a [wholesale and manufacturing license](#) in the context of parallel distribution?
15. How and where shall I mention the [parallel distributor and repackager](#) on the medicinal product?
16. Do I have to mention the [manufacturer](#) on the outer labelling?
17. Can I identify [more than one repackager](#) in the initial PD notification for a centrally authorised product?
18. Can I distribute a centrally authorised product to and from [Iceland, Norway and Liechtenstein](#)?
19. When shall I submit a PD [notification of a change](#)?
20. How shall I [present](#) my PD notification of a change?
21. How and to whom shall I [submit](#) my PD notification of a change?
22. How shall my notification of a change be handled ([timetable](#))?
23. Am I allowed to include [several languages](#) on the pack of a PD medicinal product?
24. Does the EMEA accept [combined Package leaflet](#) in a PD medicinal product?
25. Can I use a [parallel distributor specific code](#) to the proposed packaging material?
26. Can the EMEA request an [inspection](#) of a Parallel distributor?
27. Is the EMEA involved in the [registered trademark matters](#)?
28. Do I have responsibilities in the event of a [quality defect](#)?
29. Does the EMEA provide information on notifications received to [third parties](#)?
30. Does the '[Specific Mechanism](#)' agreed upon by the EU and the acceding countries apply to parallel distribution?

## Parallel distribution notifications

### 1. Is it possible to distribute a centrally authorised medicinal product from one EU Member State into another?

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. In addition, for centrally authorised medicinal products, the Community marketing authorisation encompasses all linguistic versions of the labelling and package leaflet of all authorised pack sizes. As a consequence, products put on the market in one Member State can be marketed in any other part of the Community by a 'parallel distributor', independent of the marketing authorisation holder (MAH).

The only changes that 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 labelling and package leaflet; change in the package size provided the proposed size falls within the scope of the Community Marketing authorisation).

This context is different from the parallel importation of medicines authorised nationally because of differences, which can exist between the marketing authorisation granted by the Member State of origin and the one granted by the Member State of destination.

One of the consequences of the automatic extension of the Community Marketing Authorisations as of 1 May 2004 is that the nationally authorised marketing authorisations that are in conflict with centrally approved medicinal product become invalid. In order to avoid any unnecessary stock-outs or shortfalls, there may be a transitional period during which both nationally authorised and centrally authorised products will co-exist on the national market.

Any importation of a previously nationally authorised medicinal product, which has become centrally approved after the accession date of 1 May 2004, would qualify as parallel importation and not as parallel distribution. Such importations should be dealt with by national competent authorities.

### References

- Commission Communication on the Community marketing authorisation procedures for medicinal products (98/C 229/03) OJ C 229 of 22 July 1998
- PERF III Acquis Working Group, Reflection Paper on organisational aspects of Phasing in of Commission decisions concerning centrally authorised products in new Member States.

## 2. Is the EMEA Parallel Distribution (PD) notification procedure mandatory?

Regulation 726/2004 (EC) of the European Parliament and the Council laying down Community procedures for the supervision of medicinal products and establishing the EMEA” establishes the following task for the EMEA:

*“Checking that the conditions laid down in Community legislation on medicinal products and in the marketing authorisations are observed in the case of parallel distribution of medicinal products authorised in accordance with this Regulation”.*

By the entry into force of this Regulation on 20 May 2004, notifications of parallel distribution of centrally authorised medicinal products have become mandatory throughout the Community. Therefore, on that date, all parallel distributed medicinal products on the market in the Community need to comply with the mandatory requirement involving notification to the EMEA.

### References

- Regulation 726/2004 (EC) of the European Parliament and of the Council of 31 March 2004 laying down Community Procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136 30.04.2004), Art. 57(o).

### 3. How shall I present my PD initial notification?

- In order to facilitate validation PD notifications should be presented as follows, preferably in a plain plastic sleeve, not stapled.
- Cover letter
- The “Notification of parallel distribution of a centrally authorised medicinal product” form signed and dated by the official contact person.
- Information relating to the proposed PD notification, in particular:
  - Details of the parallel distributor
  - Details of the contact person in case of quality problems and defective batches
  - Details of the medicinal product (i.e. invented name, strength, pharmaceutical form) and authorisation number in the Community register of medicinal products (i.e. EU number)
  - Details of the MAH
  - The Member State(s) of destination (choose from: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, United Kingdom)
  - Details of the Repackager
  - Certification that the condition of the product has not been affected
  - Confirmation that the fee of 3,480 EURO has been paid.
  - Signature on the form
  - The applicability of the ‘Specific Mechanism’ to the concerned notification. (See also [“Does the ‘Specific Mechanism’ agreed upon by the EU and the acceding countries apply to parallel distribution?”](#))

And annexed to the form:

- Mock-ups<sup>1</sup> of the package leaflet of the medicinal product as proposed by the parallel distributor (2 copies), or if available, 2 printed package leaflets<sup>2</sup> clearly mentioning the date of the Commission Decision texts used.
- Mock-ups of the outer and inner packaging of the medicinal product as proposed by the Parallel distributor (2 copies, in colour) or, if available, 2 colour copies<sup>2</sup> (e.g. scan or photograph) of the repackaged medicinal product<sup>3</sup> (including outer, inner packaging). (See also [“Do I need to submit colour copies and printed package leaflets of the repackaged presentation in my initial notification?”](#))
- A full copy of the original Wholesale distribution license (within the meaning of Art 77 of Directive 2001/83/EC or Art. 65 of Council Directive 2001/82/EC)
- Or a full copy of the original Manufacturing Authorisation (within the meaning of Art 40 of Directive 2001/83/EC or Art. 44 of Council Directive 2001/82/EC) or both if the repackager is different from the Parallel distributor
- **Proof of payment**

**NEW:**

The licenses should be submitted with the first notification to the EMEA and then again, whenever these are updated/amended.

**NEW:**

It is also recommended to enclose an English translated version of the authorisation(s) in addition to the copy of the original one to facilitate their review and validation by the EMEA Inspection Sector.

---

<sup>1</sup> A “Mock-up” is a copy of the label or flat artwork design in full colour, providing a replica of both the outer and immediate packaging and labelling text of the medicinal product. It is generally referred to as a “paper copy” or “computer generated version”.

<sup>2</sup> A colour copy is a digital scan or photograph of the (repackaged) sale presentation of the medicinal product. **The printed package leaflet must be representative (content and format) of the sale presentation.**

<sup>3</sup> If not available at the time of notification, the printed package leaflet and colour copies of the repackaged specimen will need to be provided to the EMEA before issuance of the notice

It should be noted that the responsibility for the quality of the submitted documentation lies with the parallel distributors and is crucial to the overall process. In doubt, parallel distributors are advised to contact the EMEA PD Secretariat.

Similarly, deficient and missing documentation can lead to a 'Request for missing information' letter, and ultimately to the non-validation of the notification. (See ["How shall my initial PD notification be handled \(timetable\)?"](#))

## References

- Commission Communication on the Community marketing authorisation procedures for medicinal products (98/C 229/03) OJ C 229 of 22 July 1998
- Notification of parallel distribution of a centrally authorised medicinal product form

#### **4. How and to whom shall I submit my initial PD notification?**

Parallel distribution notifications should be addressed and sent to the attention of the Parallel Distribution Secretariat at the following address:

EMA - Human Post-Authorisation Unit  
Parallel Distribution Secretariat  
7, Westferry Circus  
Canary Wharf  
London E14 4HB  
UK

Two paper copies of the PD notification form and supportive documentation should be submitted to the EMA.

#### **References**

- Commission Communication on the Community marketing authorisation procedures for medicinal products (98/C 229/03) OJ C 229 of 22 July 1998

## 5. When shall I submit my initial PD notification?

Parallel distributors must submit their initial notification to the EMEA in advance of commencing distribution of a specific product so as to allow for the procedure to be completed. (See [“How shall I present my PD initial notification?”](#))

Experience has shown that the average overall handling time necessary for parallel distributors to obtain the Notice is around 3 months. However, nothing precludes a faster review.

### References

- Commission Communication on the Community marketing authorisation procedures for medicinal products (98/C 229/03) OJ C 229 of 22 July 1998

## 6. How shall my initial PD notification be handled (timetable)?

### Validation

Upon receipt of an initial PD notification, the EMEA will check its validity within 5 working days and inform the parallel distributor of the start of the regulatory check or of any missing or incorrect information.

The PD Secretariat will check compliance with the date of latest annexes to the Community marketing authorisation for the product at validation stage. In case the date on the proposed package leaflet (PL) is not corresponding with the date of the latest marketing authorisation of the concerned medicinal product, the relevant annexes will be provided together with the 'Request for further information' letter.

Receipt of PD notification and fee	Day x
Start of EMEA validation	Day x+1
EMEA validation	Day x+5

In case of missing information, this period will be extended until receipt of all relevant information.

### Regulatory Check

The EMEA will check the conformity of the proposed labelling and package leaflet with the text of the latest annexes to the Community marketing authorisation within 30 working days after validation of the notification and will notify the parallel distributor of any objections or comments.

The procedure will be suspended (Clock Stop) until receipt of revised proposals for labelling and/or package leaflet.

A new cycle of 30 working days applies each time the parallel distributor (re-) submits updated labelling and/or PL proposals in accordance with the latest annexes to the Community marketing authorisation and with the EMEA comments.

The EMEA will ask parallel distributors to provide 2 printed package leaflets and 2 colour copies of the repackaged specimen (including outer, inner packaging) before issuance of the EMEA notice in case these were not available at the time of the notification.

### EMEA Notice

When there are no objections or when objections have been completely addressed by the parallel distributor, the EMEA issues a Notice and sends it to the parallel distributor, the National Authority of the Member State of destination and the marketing authorisation holder (MAH) of the medicinal product, informing that the regulatory check has been completed and indicating that the product proposed for parallel distribution complies with the terms of the Community Marketing Authorisation of the concerned centrally authorised medicinal product.

### **References**

- Commission Communication on the Community marketing authorisation procedures for medicinal products (98/C 229/03) OJ C 229 of 22 July 1998
- Notification of parallel distribution of a centrally authorised medicinal product form

## 7. Where can I obtain the latest texts for labelling and package leaflet for a given centrally authorised product?

Parallel distributors must ensure that the proposed labelling and package leaflet is in conformity with the latest annexes to the Community marketing authorisation for a given centrally authorised product.

Relevant annexes to the marketing authorisation for centrally authorised products can be obtained from the EMEA Parallel Distribution Secretariat upon written request to the attention of: [paralleldistribution@emea.eu.int](mailto:paralleldistribution@emea.eu.int). The Parallel Distribution Secretariat will provide such texts within 5 working days.

**NEW:**

**Note:** the EMEA prospectively provides the latest annexes to Community marketing authorisation for a given product to all parallel distributors that have a validated Notification for that product. This service is provided to parallel distributors to help them to maintain the labelling and package leaflet of the repackaged medicinal products in conformity with the latest annexes to the Community marketing authorisation. Parallel distributors who receive that information should save it upon receipt as individual requests for the same information will not be processed by the EMEA.

These annexes are also included in the European Public Assessment Report(s) (EPARs) available in all EU official languages on the EMEA website:

<http://www.emea.eu.int> under Human medicines/List of authorised products (EPARs).

### References

- Commission Communication on the Community marketing authorisation procedures for medicinal products (98/C 229/03) OJ C 229 of 22 July 1998

**8. Is there any deviation allowed to the texts of the Commission Decision for a certain product?**

In respect of the package leaflet and labelling (inner and outer) the EMEA checks the strict compliance of the parallel-distributed product with the terms of the Community Marketing Authorisation for the centrally authorised medicinal product and in the language concerned.

Apart from the mentioning of the 'parallel distributor', the 'repackager' and the 'MAH's manufacturer' on the outer labelling, the only additional flexibility given is in respect to the terms used for expressing the batch number and expiry date. (See "[Do I have to mention the MAH's manufacturer on the outer labelling?](#)" and "[How and where shall I mention the parallel distributor and repackager on the medicinal product?](#)")

The parallel distributor is allowed to use any of the terms listed in the QRD document "Tables of Non-standard Abbreviations" (EMEA/27236-v3.0) for a certain Member State.

**References**

- Tables of Non-standard Abbreviations (EMEA/27236-v3.0)

## 9. Can I interchange multiple licenses in the context of parallel distribution?

The EMEA checks the compliance of the parallel-distributed product with the terms of the Community Marketing Authorisation for the concerned centrally authorised product in the language concerned.

Since this Community marketing authorisation is specific for a given centrally authorised product to be marketed under that particular invented name it is not acceptable for the parallel distributor to interchange them in the context of parallel distribution.

Parallel distributors wishing to distribute products which are available on the Community market under two or more invented names, need to submit to the EMEA a separate PD notification for each centrally authorised product.

Moreover, in accordance with Community legislation the name given to a medicinal product by the company may be either a) an invented name (brand name/trade name) or b) a common/scientific name together with the name of the manufacturer.

Since this means that the originator MAH is not allowed to interchange these, flexibility in this respect to a parallel distributor is also not allowed.

The same principle applies as to the use of the active substance description of the product.

### References

- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.
- Guideline on the acceptability of invented names for human medicinal products processed through the centralised procedure (CMPM/328/98)

**10. Can I propose a bundle-pack<sup>1</sup> of existing presentations in the context of parallel distribution?**

The EMEA does not accept any proposals from parallel distributors to bundle existing presentations of a centrally authorised product to create a larger pack-size, even if this pack-size is covered by the Community marketing authorization of the concerned medicinal product.

The reason is that the different presentations are subject to separate central marketing authorisations.

**References**

- ECJ (C-433/00) Aventis v Kohlfarma
- Notification of parallel distribution of a centrally authorised medicinal product form

---

<sup>1</sup> “Joining together of several packages of medicinal products, each leaving the necessary labelling in order to form a new retail unit”

## 11. How many PD notifications shall I submit for a given medicinal product?

The parallel distributor is only allowed to distribute presentations that are covered by the Community Marketing Authorisation for that particular centrally authorised medicinal product.

**Update:**

A separate notification should be submitted for each strength and pharmaceutical form of a given medicinal product (Several pack sizes for a given strength and form can be included in the same notification). (See also ["How shall I present my PD notification/notification of a change"](#))

### References

- Notification of parallel distribution of a centrally authorised medicinal product form

## 12. What fee do I have to pay for an initial PD notification?

An administrative charge of 3,480 EURO applies for each initial **validated** PD Notification. This charge covers all pack-sizes of a particular strength and pharmaceutical form for a given medicinal product.

### **Update:**

Parallel distributors are strongly advised to ensure that the relevant fees arrive at the EMEA bank account at the latest on the same day as the receipt of the PD notification. Once the notification with the supporting documentation and correct fee has been received, the regulatory check will start the next EMEA working day. (See "[How shall my initial PD notification be handled \(timetable\)?](#)")

Missing payment at the time of the validation of a given PD notification will lead to a 'Request for missing information' letter and, **ultimately, to the non-validation of the Notification**. (See "[How shall I present my PD initial notification?](#)")

### **Update:**

For more information about fees and fee payment, please consult:

<http://www.emea.eu.int/htms/general/admin/fees/feesfaq.htm>,

<http://www.emea.eu.int/htms/general/admin/fees/payaddresspara.htm>

## References

- Notification of parallel distribution of a centrally authorised medicinal product form
- Explanatory note on fees payable to the EMEA (EMEA/H/5913/03)
- EMEA Information on the revision of Parallel distribution Administrative Charges and clarification regarding the procedure to be followed when adding a country of destination ([EMEA/Ho/13397/04](#))

**13. Do I need to submit colour copies and printed package leaflets of the repackaged presentation with my initial PD notifications?**

**Update:**

Colour copies of the outer and inner packaging, and a printed package leaflet of the repackaged sales presentation will be requested by the EMEA within the initial notification, if available or before issuance of the EMEA Notice. (See also [“How shall I present my PD notification?”](#))

Where the quality of the provided colour copies is not considered acceptable, the EMEA may request the submission of revised ones.

**References**

- Joined cases C-427/93, C-429/93 and C-436/93, *Bristol-Myers Squibb and others / Paranova* (Rec.1996,p.I-3457), para. 79.

#### 14. Do I need a wholesale distribution and manufacturing license in the context of parallel distribution?

All parties need to hold the appropriate licences for the activities in which they are engaged i.e. a wholesale distribution authorisation and/or manufacturing authorisation.

The ECJ has defined 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”, as repackaging and will therefore always require a valid manufacturing authorisation.

These repackaging activities can be carried out by the parallel distributor or may be outsourced to another company, subject in either case to the holding of a valid manufacturing authorisation. In the case of human medicinal products a manufacturing authorisation may permit the wholesale distribution of products covered by that license.

A parallel distributor is normally engaged in activities defined as wholesale distribution and will need to hold a wholesale distribution authorisation.

A copy of the complete original authorisation(s) (with attachments) should be enclosed with the first PD notification. It is also recommended to enclose an English translated version of the authorisation(s) to facilitate their review and validation by the EMEA Inspection Sector. A copy of any update or amendments to these licences occurring after issuance of the Notice should be provided to the EMEA as soon as possible.

#### References

- Art 77 of Directive 2001/83/EC or Art. 65 of Council Directive 2001/82/EC - Wholesale distribution license
- Art 40 of Directive 2001/83/EC or Art. 44 of Council Directive 2001/82/EC - Manufacturing Authorisation
- Art. 77(3) of Directive 2001/83/EC
- Case C-232/94, MPA Pharma / Rhône-Poulenc Pharma (Rec.1996,p.I-3671) Joined cases C-427/93, C-429/93 and C-436/93, Bristol-Myers Squibb and others / Paranova (Rec.1996,p.I-3457), para. 79. C-71/94, *Eurim-Pharm Arzneimittel / Beiersdorf and others* (Rec.1996,p.I-3603)
- Commission Communication on the Community marketing authorisation procedures for medicinal products (98/C 229/03) OJ C 229 of 22 July 1998
- Notification of parallel distribution of a centrally authorised medicinal product form

## 15. How and where shall I mention the parallel distributor and repackager on the medicinal product?

ECJ case law requires the repackager and the MAH manufacturer to be identified on the medicinal product. In addition, the EMEA recommends the mentioning of the 'parallel distributor' on the medicinal product as follows:

### Outer labelling

On the outer labelling the following text should be added (in the language(s) of the member state of destination):

**NEW:** *"Parallel distributed and repackaged by.... (name is mandatory, address is recommended but not compulsory)"* - in case parallel distributor and repackager are identical.

*"Manufacturer: ....(name is mandatory, address is recommended but not compulsory)"*

*"Parallel distributed by... (name and address are recommended but not compulsory)"* and *"Repackaged by ..... (name is mandatory, address is recommended but not compulsory)"* - in case parallel distributor and repackager are different.

*"Manufacturer: ....(name is mandatory, address is recommended but not compulsory)"*

Where the parallel distributor has notified more than one repackager in this notification, he should ensure to only mention on the outer label the repackager for the concerned batch. (See also: ["Can I identify more than one repackager in the initial PD notification for a centrally authorised product?"](#) and ["Do I have to mention the manufacturer on the outer labelling?"](#))

### Inner labelling

If practical, the name of the parallel distributor and repackager should preferably be included on the inner labelling as well, but it is not compulsory.

It is acceptable to only mention the name:

*"Parallel distributed and repackaged by.... (name)"* - in case parallel distributor and repackager are identical

*"Parallel distributed by... (name)"* and *"Repackaged by ..... (name)"* - in case parallel distributor and repackager are different

Where the parallel distributor has notified more than one repackager in this notification, he should ensure to only mention on the inner label the repackager for the concerned batch. (See also: ["Can I identify more than one repackager in the initial PD notification for a centrally authorised product?"](#))

### Package leaflet

Reference to the 'parallel distributor' and 'repackager' is allowed in the package leaflet. The manufacturer of the MAH is already mentioned in the Package Leaflet.

### References

- Joined cases C-427/93, C-429/93 and C-436/93, *Bristol-Myers Squibb and others / Paranova* (Rec. 1996,p.I-3457)
- Notification for parallel distribution of a centrally authorised medicinal product form

## 16. Do I have to mention the manufacturer on the outer labelling?

Community Law, as complemented by ECJ case law requires the parallel distributor to mention the manufacturer of the MAH on the medicinal product.

The parallel distributor should mention the manufacturer responsible for the release of the concerned batch, as it appears in the package leaflet of the original batch (i.e. member state of origin).

**NEW:**

Note: The annexes to the Community marketing authorisation may mention several MAH manufacturers. This is because the MAH has to mention all its authorised manufacturers in the annexes approved by the European Commission. However, in the printed package leaflet (i.e. package leaflet of the original batch of the member state of origin), the MAH has to specify the manufacturer responsible for the release of the concerned batch. Therefore, the parallel distributor should refer to the package leaflet of the original batch and not to the annexes to the Community marketing authorisation to identify the relevant manufacturer to be mentioned on the packaging.

(See also: [“How and where shall I mention the parallel distributor and repackager on the medicinal product?”](#))

### References

- Directive 2001/83/EC, Article 54
- ECJ cases.  
*C-443/99, Merck, Sharp & Dohme (Rec.2002,p.1-3703)*  
*C-102/77, Hoffman-La Roche / Centrafarm (Rec.1978, p.1139)*  
*(GR1978/00351 P 1978/00391 ES1978/00317 SVIV/00107 FIIV/00107)*
- Commission Communication on the Community marketing authorisation procedures for medicinal products (98/C 229/03) OJ C 229 of 22 July 1998

**17. Can I identify more than one repackager in the initial PD notification for a centrally authorised product?**

**Update:**

Parallel distributors are allowed to identify more than one repackager in the initial PD notification provided they include two separate sets of mock-ups, each clearly identifying one of the repackagers, **and a copy of the Manufacturing Authorisation for each repackager.**

For the proposed outer labelling on the medicinal product, the parallel distributor must state the name (**and optionally the address**) of the repackager responsible for the release of that particular batch.

For the proposed inner labelling on the medicinal product, the parallel distributor is allowed to only mention the name of the repackager responsible for the release of that particular batch. (See also: "[How and where shall I mention the parallel distributor and repackager on the medicinal product?](#)")

The parallel distributor may also submit a 'notification of change' in order to include an additional repackager.

**References**

- Notification of parallel distribution of a centrally authorised medicinal product form
- Notification of a change for parallel distribution of a centrally authorised medicinal product form

## **18. Can I distribute a CAP to or from Norway, Iceland and Liechtenstein?**

The principles laid down in section D of Commission Communication 98/C229/03 on the Community marketing authorisation procedures for medicinal products apply.

The EMEA notification procedures for parallel distribution will also apply for parallel distribution from Iceland, Norway and Liechtenstein, provided the products have been previously harmonised with the Community marketing authorisation.

Parallel distributors are strongly recommended to consult the EMEA prior to submission of a PD notification to ensure that the given product are effectively harmonised in these countries.

For parallel import into Iceland, Norway and Liechtenstein, the national procedures for parallel import apply.

### **References**

- Commission Communication on the Community marketing authorisation procedures for medicinal products (98/C 229/03) OJ C 229 of 22 July 1998
- EEA Joint Committee Decision 74/1999
- Guidance document for Industry, with regard to the extension of the centralised procedure, referral procedures, parallel distribution/import and pharmacovigilance requirements to Iceland and Norway (EMEA/8518/00 Rev 1)

## 19. When shall I submit a notification of a change?

Parallel distributors must ensure that the proposed labelling and package leaflet remain in conformity with the latest annexes to the Community marketing authorisation for the product concerned. For this purpose, the EMEA will prospectively provide the latest annexes to Community marketing authorisation for a given product to all parallel distributors that have already obtained a Notice for that product.

Where amendments have been made to the annexes of the Community marketing authorisation for a centrally authorised medicinal product, or when the parallel distributor wants to change information submitted in the initial PD notification (e.g. change in repackager or parallel distributor details), the parallel distributor should submit a “Notification of a change” form, stating the scope of change.

In addition, a notification of a change must be submitted when the parallel distributor wants to amend the country(ies) of origin.

The “Notification of a change for parallel distribution of a centrally authorised medicinal product” form can be downloaded from the EMEA website: <http://www.emea.eu.int/> under human medicines/regulatory guidance and procedures/parallel distribution/guidance and templates.

**Note:** A Notification of a change can only be submitted after obtaining an EMEA Notice for the initial PD notification.

### References

- Notification of change for parallel distribution of a centrally authorised medicinal product form

## 20. How shall I present my PD notification of a change?

In order to facilitate validation PD notifications should be presented as follows, preferably in a plain plastic sleeve, not stapled.

- Cover letter
- The “Notification of a change for parallel distribution of a centrally authorised medicinal product” form signed and dated by the official contact person.
- Information relating to the proposed PD notification, in particular:
  - Details of the parallel distributor
  - Details of the contact person in case of quality problems and defective batches
  - Details of the medicinal product (i.e. invented name, strength, pharmaceutical form) and authorisation number in the Community register of medicinal products (i.e. EU number)
  - Details of the MAH
  - Scope of the change
  - Signature on the form
  - The applicability of the ‘Specific Mechanism’ to the concerned notification of a change. (See also [“Does the ‘Specific Mechanism’ agreed upon by the EU and the acceding countries apply to parallel distribution?”](#))

And annexed to the form:

- A printed package leaflet of the medicinal product as proposed by the parallel distributor, clearly mentioning the date of the latest marketing authorisation texts used. (if applicable)
- One colour copy (e.g. scan or photograph) of the repackaged presentation (including outer and inner packaging). (if applicable).
- The licenses should only be submitted in a notification of a change whenever they are updated/amended compared to the one submitted initially.

It should be noted that the responsibility for the quality of the submitted documentation lies with the parallel distributor and is crucial to the overall process. In particular, the notification of a change form must be duly completed, signed and dated. In doubt, parallel distributors are advised to contact the EMEA PD Secretariat.

Similarly, deficient and missing documentation can lead to ‘request for missing information’ letter, and ultimately to the non-validation of the notification of a change. (See [“How shall my notification of a change be handled \(timetable\)?”](#))

**Update:**

### References

- Commission Communication on the Community marketing authorisation procedures for medicinal products (98/C 229/03) OJ C 229 of 22 July 1998
- Notification of change for parallel distribution of a centrally authorised medicinal product form

## **21. How and to whom shall I submit my PD notification of a change?**

PD notifications should be addressed and sent to the attention of Parallel Distribution Secretariat at the following address:

EMA - Human Post-Authorisation Unit  
Parallel Distribution Secretariat  
7, Westferry Circus  
Canary Wharf  
London E14 4HB  
UK

Two paper copies of the PD notification form and supportive documentation should be submitted to the EMA.

### **References**

- Commission Communication on the Community marketing authorisation procedures for medicinal products (98/C 229/03) OJ C 229 of 22 July 1998
- Notification of a change for parallel distribution of a centrally authorised medicinal product form

## 22. How shall my notification of a change be handled (timetable)?

A notice of a change is only issued for changes not related to the update of annexes to the Community marketing authorisation. The notice of a change will be transmitted within 5 working days to the parallel distributor, the relevant competent authority and the MAH of the concerned product.

For notifications of change solely related to the update of annexes to the latest Community marketing authorisation, the EMEA will only acknowledge receipt of the notification of a change within 5 working days. Nevertheless, parallel distributors have to file a notification of a change form and to provide a printed package leaflet and a colour copy of the repackaged specimen (outer/inner labelling). Instead of performing a detailed check of the updated labelling and/or package leaflet, the EMEA performs a "spot-check" system. Where the outcome of such spot-check is considered unsatisfactory, the parallel distributor may be obliged to use a prospective notification of a change review process.

Receipt of PD notification	Day x
EMEA acknowledgement of receipt and/or notice of a change	Day x+5

### References

- Commission Communication on the Community marketing authorisation procedures for medicinal products (98/C 229/03) OJ C 229 of 22 July 1998
- Notification of a change for parallel distribution of a centrally authorised medicinal product form

### **23. Am I allowed to include several languages on the pack of a PD medicinal product?**

The Community pharmaceutical legislation mentions that the particulars shall appear in the official language or languages of the member state where the product is placed on the market.

This provision shall not prevent these particulars from being indicated in several languages, provided that the particulars appear in all the languages used.

The labelling and package leaflet texts used by the parallel distributor should be in accordance with the texts of the Commission Decision granting or amending the marketing authorisation for the medicinal product concerned in all languages chosen.

If the Parallel distributor wishes to create multilingual packs suitable for distribution in different Member States of destination, this would require the submission of a separate notification per Member State of destination.

#### **References**

- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. Title V. Labelling and Package Leaflet.

#### **24. Does the EMEA accept combined package leaflet in a PD product?**

The EMEA accepts parallel distributors to use combined printed package leaflet (PL) for their centrally authorised products provided that the originator product already includes a combined printed PL.

A copy of the original combined PL should be included in the initial PD notification or notification of a change.

The reason for the request of a copy of the original PL is that combined printed PL can only be acceptable if the three conditions described in the “Compilation of QRD decisions on stylistic matters in the product information” are met and the applicant of the centrally authorised product or the MAH submits a request to the Quality Review Documents (QRD) Group, together with a justification/rationale. A decision is then taken by the QRD on a case-by-case basis.

#### **References**

- Compilation of QRD decisions on stylistic matters in the product information (version 7.0, EMEA 07/2003).

## **25. Can I use a parallel distributor specific code to the proposed packaging material?**

The addition of a parallel distributor internal code to packaging material is considered by the EMEA as good practice and therefore acceptable, provided it is not being presented as part of the core-text of the labelling and package leaflet. The original batch number must always be retained.

This includes the mentioning of a "re-pack batch" or the addition of a prefix or suffix to the original batch number to reflect additional repackaging activities.

### **References**

- Directive 2001/83/EC – Title V – Labelling and package leaflet
- Eudralex Volume 4 article 5.44-57

## **26. Can the EMEA request an Inspection of a Parallel distributor?**

The EMEA does not request inspections of parallel distributors.

The EMEA Inspections sector will check the validity of the wholesale, distribution and manufacturing licenses submitted as part of validation of a PD notification.

Where considered necessary, the EMEA Inspections Sector can inform the inspection services of the competent National Authority on any issue that has been brought to its attention.

The responsibility for any actions, however, remains with the competent authorities of the respective Member States.

### **References**

- Commission Communication on the Community marketing authorisation procedures for medicinal products (98/C 229/03) OJ C 229 of 22 July 1998

## 27. Is the EMEA involved in registered trademark matters?

The EMEA only checks the compliance of the parallel-distributed product with the terms of the Community Marketing Authorisation for the concerned centrally authorised product. The annexes to the Commission Decision do not include any registered or trademark symbols.

According to European Court of Justice of the European Communities - Case C-232/94 case law parallel distributors have the obligation to *"give notice to the trademark owner before the repackaged product is put on sale, and, on demand, supplies him with a specimen of the repackaged product."*

In accordance with ECJ case law it is up to the Trade Mark owner to check if the presentation after repackaging is not such as to damage the reputation of the Trade Mark owner.

The EMEA does not oppose nor impose the use of registered trademark symbols.

### References

- Case C-232/94, *MPA Pharma / Rhône-Poulenc Pharma* (Rec.1996, p.I-3671)
- Joined cases C-427/93, C-429/93 and C-436/93, *Bristol-Myers Squibb and others / Paranova* (Rec.1996,p.I-3457)

## 28. Do I have responsibilities in the event of a quality defect?

In the case of products which have been subject to parallel distribution a defect may become apparent due to a problem with the original product as it left the manufacturer, or as a result of subsequent handling in the distribution chain, particularly where the packaging material, including the patient leaflet, has been changed. In either case the parallel distributor has responsibilities.

1. A parallel distributor can make changes to the packaging materials of a product only if it holds a manufacturing authorisation<sup>1</sup> issued by the relevant national competent authority. It is therefore bound to the provisions of that authorisation, which include compliance with the principles and guidelines of Good Manufacturing Practice (GMP) that are laid down in Directives 2003/94/EC and 91/412/EEC, for human and veterinary products respectively. Manufacturers are required to have a system for recording and reviewing complaints and for effective recall. A manufacturer is obliged to inform the competent authority of any defect it has become aware of that might result in a recall or abnormal restriction in supply and this applies equally to parallel distributors. The competent authority will assist the parallel distributor in the recall process and will initiate the rapid alert<sup>2</sup> system accordingly. A parallel distributor should ensure that the marketing authorisation holder is informed of any recall initiated by the parallel distributor.
2. Parallel distributors must procure product only from a holder of a wholesale distribution authorisation<sup>3</sup> in the source member state. The supplier is consequently obliged to inform the parallel distributor of any recall activity originating with the supplier or earlier in the distribution chain including the original manufacturer that might involve products supplied to the parallel distributor. Such notifications must be handled within the parallel distributor's GMP system to confirm whether the affected product was actually received, trace its utilisation and initiate recall procedures as necessary, including contacting the local competent authority.

### References

- Art. 44 Directive 2001/82/EC, or Art. 40 Directive 2001/83/EC
- Art. 65 Directive 2001/82/EC, or Art. 77 Directive 2001/83/EC
- Revised compilation of community procedures on administrative collaboration and harmonisation of inspections - Procedure for Handling Rapid Alerts and Recalls Arising from Quality Defects – October 2003

---

<sup>1</sup> Art. 44 Directive 2001/82/EC, or Art. 40 Directive 2001/83/EC

<sup>2</sup> Compilation of Community Procedures on Inspections and Exchange of Information – October 2003

<sup>3</sup> Art. 65 Directive 2001/82/EC, or Art. 77 Directive 2001/83/EC

**29. Does the EMEA provide information on notifications received to third parties?**

In the light of recent ECJ case law, the EMEA will, in accordance with its 'Procedure for notifications of parallel distribution of Centrally authorised medicinal products' (EMEA/H/30313/98 Rev 2), only send a Notice (of a change) to the parallel distributor, and a copy of the Notice (of a change) to the Member State of destination and the MAH of the medicinal product, indicating that the regulatory check has been completed.

Although the MAH may request an overview of all EMEA Notices issued for their products at any time, these will not include information on ongoing procedures.

Exceptions to the above rules are made for any request for information on parallel distribution received from a competent authority. Information as to the status of a particular notification in the process is also provided.

The EMEA does not release or publish information on the parallel distributors/products for which a Notice has been issued.

### 30. Does the 'Specific Mechanism' agreed upon by the EU and the acceding countries apply to parallel distribution?

The following text has been included in the Act of Accession:

*"With regard to the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia or Slovakia, the holder or beneficiary, of a patent or supplementary protection certificate for a pharmaceutical product filed in a Member State at a time when such protection could not be obtained in one of the above-mentioned new Member states for that product, may rely on the rights granted by that patent or supplementary protection certificate in order to prevent the import and marketing of that product in the Member State or States where the product in question enjoys patent protection or supplementary protection, even if the product was put on the market in that new Member State for the first time by him or with his consent.*

*Any person intending to import or market a pharmaceutical product covered by the above paragraph in a Member State where the product enjoys a patent or supplementary protection shall demonstrate to the competent authorities in the application regarding that import that one month's prior notification has been given to the holder or beneficiary of such protection."*

For a limited period after accession, some medicines on the market in the new EU Member States will not have the same level of intellectual property right protection found in the existing EU Member States. The Accession Treaties therefore introduced the above mentioned transitional period to the full application of the principle of the free movement goods to prevent parallel trade in pharmaceutical products that lack equivalent intellectual property right protection. The mechanism also introduces the requirement that parallel traders have to provide confirmation to the competent authority that they have informed the patent holder one month in advance of a notification for a parallel distribution. However, the legal responsibility for enforcing intellectual property rights will remain with the patent holder.

When submitting a notification (of a change) to the EMEA, parallel distributors are required to specify the country(ies) of origin and of destination of the medicinal product they intend to parallel distribute and to specify whether the specific mechanism applies to the concerned notification. Parallel distributors are also requested to confirm that the patent holder or beneficiary has been given one month's advance notice in their application when the specific mechanism applies.

In case the specific mechanism does not apply, parallel distributors will commit to submit a Notification of a change should they subsequently initiate parallel distribution from countries where the specific mechanism applies. In addition, parallel distributor will commit to ensure that the patent holder or beneficiary will be given one month's advance notice in their application.

#### References

- Annex IV(2) of the Act of Accession signed on 16th of April 2003
- Notification of parallel distribution of a centrally authorised medicinal product form
- Notification of a change for parallel distribution of a centrally authorised medicinal product form