ΚΥΠΡΙΑΚΗ ΔΗΜΟΚΡΑΤΙΑ
ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ

ΦΑΡΜΑΚΕΥΤΙΚΕΣ ΥΠΗΡΕΣΙΕΣ
1475 ΛΕΥΚΩΣΙΑ

Αρ. Φακέλου: 05.21.02.01 & 5.13.2.2
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11 January 2018

Μέσω ηλεκτρονικού ταχυδρομείου (e-mail)

English Text Follows

Προς όλους τους: Κατόχους Αδειών Κυκλοφορίας (ΚΑΚ) Φαρμακευτικών Προϊόντων και Τοπικούς Αντιπροσώπους

Θέμα: Έγγραφα που απαιτούνται για την Μεταφορά Άδειας Κυκλοφορίας

Επιθυμώ να αναφερθώ στο πιο πάνω θέμα και να σας πληροφορήσω ότι το Συμβούλιο Φαρμάκων σε συνεδρία του ημερομηνίας 01/11/2017 αποφάσισε τα ακόλουθα:

- Την αναθεώρηση των απαραίτητων δικαιολογητικών που απαιτείται να συνοδεύουν μια αίτηση για μεταφορά άδειας κυκλοφορίας ενός φαρμακευτικού προϊόντος σε νέο κάτοχο άδειας κυκλοφορίας. Παρακαλείσθε όπως ανατρέξετε στις πιο κάτω σελίδες για τις αναθεωρημένες απαιτήσεις. Αυτές αντικαθιστούν τον κατάλογο που δημοσιεύθηκε τον Ιανουάριο του 2013.

Ε. Μαυροκορδάτου
Έφορος Συμβουλίου Φαρμάκων

REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

PHARMACEUTICAL SERVICES
1475 NICOSIA

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11 January 2018

Via Electronic mail

To: Marketing Authorisation Holders and Local Representatives

Subject: List of documents required for Marketing Authorisation Transfer

With regards to the above mentioned subject, please note that the Drug Council during its meeting dated 01/11/2017 has decided the following:

- The revision of the necessary documentation required to accompany an application for the transfer of a marketing authorisation of a medicinal product to a new marketing authorisation holder. Please refer to the following pages for the updated requirements. These are in replacement of the list published on January 2013.

REPUBLIC OF CYPRUS
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MINISTRY OF HEALTH
PHARMACEUTICAL SERVICES
1475 LEFKOSIA

NECESSARY DOCUMENTATION REQUIRED TO ACCOMPANY AN APPLICATION FOR THE TRANSFER OF A MARKETING AUTHORISATION OF A MEDICINAL PRODUCT TO NEW MARKETING AUTHORISATION HOLDER

This variation should be submitted under classification A.z as Type II.

Implementation date: after a valid approval.

All the submitted documentation should include on the filename the number of the document as indicated below.

1. Application form for a Variation, fully completed, explicitly stating the name of the medicinal product, the number and the date of issue of the marketing authorisation and complete contact details of the current and future marketing authorisation holder. The Application for a Variation is to be completed by the current marketing authorisation holder.

2. A statement by the current or the new marketing authorisation holder attesting to that a fully completed dossier of the medicinal product is in possession or at the disposal of the new marketing authorisation holder.

3. A statement from the new marketing authorisation holder affirming his intention and competence to undertake the marketing authorisation from a specified date onwards.

4. The necessary documentation attesting to that the new marketing authorisation holder is competent to undertake the marketing authorisation and all the responsibilities it carries e.g.
    a. Certificate of founding of the company from the Registrar of Companies - Proof of establishment of the new Marketing Authorisation Holder within the EEA.
    b. A document identifying the contact details of the person responsible for Pharmacovigilance in Cyprus (full documentation needs to be appended) (see number 6) including the name, address, telephone, fax and email address, together with his/her Curriculum Vitae.
    c. A document identifying the contact details of the person responsible for Scientific Service in Cyprus including the name, address, telephone, fax and email address, together with his/her Curriculum Vitae.
    d. A document identifying the contact details of the person responsible for Defects & Recalls including the name, address, telephone, fax and email address.
    e. A document identifying the contact details of the person authorised for communication with the authorities on behalf of the new Marketing Authorisation Holder including the name, address, telephone, fax and email address.
    f. A document identifying the contact details of the local representative including the name, address, telephone, fax and email address. If a local representative is not available, a declaration letter indicating that should be submitted.
    g. Documentation for the size, personnel and organisation of the company.

5. The SPC, PIL & Labelling (working documents – clean version & track changes version as well as in electronic format) in accordance to the legislation, updated to include the new marketing authorisation holder should be submitted.
   Mock-ups (primary and secondary packaging) in accordance to the legislation, updated to include the new marketing authorisation holder should be submitted in electronic format.
   Mock-ups (primary and secondary packaging) concerning all the registered pack-sizes should be submitted. In case the applicant is not able to submit mock-ups for all the registered pack-sizes in Cyprus at the time of the application, it is possible to submit mock-ups only for the marketed pack-sizes in Cyprus.
   At the same time, a signed declaration letter must be submitted indicating the following:
   - The marketed pack-sizes in Cyprus.
   - The mock-ups submitted with this variation concerning only the marketed pack-sizes.
   - Committing that mock ups will be submitted via relevant notifications if the Marketing Authorisation Holder wish to market a new but already registered pack size.

   Marketed pack sizes are considered those pack sizes which have a price in Cyprus, regardless if they are actually on the market at present.

   Please note that for those pack-sizes for which mock-ups have not been submitted, a price cannot be obtained. In case a price is required in the future concerning a registered pack-size for which a mock-up has not been submitted, a notification along with the mock-ups should be submitted before the price application.

6. A document identifying the qualified person responsible for Pharmacovigilance (QPPV) within the meaning of Article 23 of Regulation (EC) No 726/2004, together with his/her Curriculum Vitae stating home address, email address, telephone and fax number. The qualified person responsible for Pharmacovigilance must be permanently and continuously at the disposal of the Transferee and must be established (reside) within the European Economic Area.

7. A copy of the agreement between the two marketing authorisation holders for the transfer of the marketing authorisation.

8. The name, address, and responsibility of each manufacturer, including contractors, and each production site or facility involved in manufacturing and testing should be provided (e.g. manufacturer responsible for the intermediate product, manufacturer responsible for the finished product, manufacturer responsible for batch control, manufacturer responsible for batch release, manufacturer responsible for primary packing, manufacturer responsible for secondary packaging).

9. The relevant fees need to accompany the application.

10. A statement from the current or new marketing authorisation holder attesting that the original marketing authorisation of the medicinal product is in possession of the new marketing authorisation holder.