REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

PHARMACEUTICAL SERVICES
1475 ΛΕΥΚΩΣΙΑ

Αρ. Φακ: 5.21.2.1.9, 05.13.001, 5.13.2.2
Αρ. Τηλ.: 22608622
Αρ. Φαξ: 22608649
E-mail : pphilippou@phs.moh.gov.cy

22/04/2024

English Text Follows

Μέσω ηλεκτρονικού ταχυδρομείου

Προς: Κατόχους Αδειών Κυκλοφορίας (ΚΑΚ) και Τοπικούς Αντιπροσώπους

Θέμα: Αλλαγή του τρόπου κατάθεσης των αιτήσεων για την έκδοση Πιστοποιητικού Φαρμακευτικού Προϊόντος (Certificate of a Pharmaceutical Product) και γενικών πιστοποιητικών πληροφοριακού περιεχομένου.

Έχω οδηγίες να αναφερθώ στο πιο πάνω θέμα και σχετική απόφαση του Συμβουλίου Φαρμάκων, ημερ. 31/01/2024, και να σας ενημερώσω πως ο τρόπος κατάθεσης των αιτήσεων για την έκδοση των πιο πάνω πιστοποιητικών, διαφοροποιείται ως ακολούθως:

1. Οι ΚΑΚ ή/και οι τοπικοί αντιπρόσωποι θα υποβάλλουν εφεξής τα εν λόγω αιτήματα **ηλεκτρονικά** στην πιο κάτω διεύθυνση:

cppsubmissions@phs.moh.gov.cy

2. Τα αιτήματα θα συνοδεύονται από:
   - Την Αίτηση έκδοσης Πιστοποιητικού Φαρμακευτικού Προϊόντος (Συνημμένο 1),
   - Το νέο έντυπο με τίτλο ¨Certificate of a Pharmaceutical Product¨ (Συνημμένο 2) ορθά συμπληρωμένο,
   - Την απόδειξη εξόφλησης των νενομισμένων τελών μέσω JCC SMART. Επισημαίνεται πως, βάσει του περί Φαρμάκων Ανθρώπινης Χρήσης (Τέλη) Διατάγματος του 2024 [Κ.Δ.Π. 132/2024, ημερ. 12/4/2024], με την υποβολή αίτησης για έκδοση οποιωνδήποτε πιστοποιητικών, καταβάλλεται το ποσό των 5,00 Ευρώ. Σημειώνεται επίσης ότι κατά την πληρωμή μέσω JCC SMART θα πρέπει να σημειώνονται υποχρεωτικά στα κατάλληλα πεδία όλα τα ονόματα των φαρμακευτικών προϊόντων στα οποία αφορά η αίτηση και η ημερομηνία υποβολής αυτής,
   - Εξουσιοδότηση ΚΑΚ (αν ο αιτητής δεν είναι ο ΚΑΚ).

3. Από την **1η Μαΐου 2024** θα γίνονται αποδεκτές **μόνο ηλεκτρονικές** καταθέσεις στο πιο πάνω ηλεκτρονικό ταχυδρομείο. Οι ΚΑΚ ή/και οι εξουσιοδοτημένοι αντιπρόσωποί τους θα πρέπει να αποστέλλουν όλα τα απαιτούμενα έγγραφα **με μόνο μία ηλεκτρονική** κατάθεση στο πιο πάνω e-mail. Οι Φαρμακευτικές Υπηρεσίες θα αποστέλλουν ηλεκτρονική απάντηση ενημερώνοντας τον αιτητή σχετικά με την έκδοση ή μη των πιστοποιητικών ή με την αναγκαιότητα περαιτέρω διευκρινήσεων ή διορθώσεων. Ο αιτητής θα ενημερώνεται μέσω e-mail για τον χρόνο παραλαβής των πιστοποιητικών από την αρμόδια λειτουργό (κ. Πόλυ Φιλίππου, τηλ. 22-608622).

Παρακαλείστε όπως προβαίνετε στην έγκαιρη κατάθεση των απαραίτητων στοιχείων ώστε να διασφαλίζεται ότι οι Φαρμακευτικές Υπηρεσίες θα έχουν στη διάθεσή τους το απαραίτητο χρονικό περιθώριο για την εξέταση των ηλεκτρονικών σας καταθέσεων και την έγκαιρη έκδοση των πιστοποιητικών.

Σημειώνεται ότι πιστοποιητικά που έχουν εκδοθεί δεν επιδέχονται διορθώσεων και οι αιτητές θα πρέπει να υποβάλλουν εκ νέου αίτηση για έκδοση πιστοποιητικού, όπου απαιτείται.

Σημειώνεται ότι τυχόν αιτήματα που δε θα υποβάλλονται ηλεκτρονικά μετά την **1η Μαΐου 2024** δε θα γίνονται αποδεκτά.

Για οποιεσδήποτε διευκρινίσεις παρακαλώ αποτείνεστε στην κ. Ειρήνη Περικλέους (ipericleous@phs.moh.gov.cy , +35722608629).

(Ειρήνη Περικλέους)
Για Έφορο Συμβουλίου Φαρμάκων

REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

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1475 ΛΕΥΚΩΣΙΑ

File No. 5.21.2.1.9, 05.13.001, 5.13.2.2
Tel: 22608622
Fax: 22608649
Email: pphilippou@phs.moh.gov

22/04/2024

Via electronic mail

To Marketing Authorisation Holders and authorised local representatives

Re: Change in the submission procedure for the applications for issuing of a Certificate of a Pharmaceutical Product and Certificates of general informational nature.

I have instructions to refer to the above subject and the Drugs Council decision dated 31/01/2024 and inform you that the submission of application concerning the issuing of a Certificate of a Pharmaceutical Product has been amended as follows:

1. Marketing authorisation holders or/and authorised local representatives should submit electronically all the applications to the following email address:

cppsubmissions@phs.moh.gov.cy

2. All the applications should include all the documents as indicated below:

- Application form for issuing Certificate of a Pharmaceutical Product (attachment 1),
- New version of the Certificate of a Pharmaceutical Product (attachment 2) duly completed,
- Proof of payment of the required fees through JCC SMART. According to the Human Medicines Use (fees) Decree 132/2024 dated 12/4/2024, the amount of €5 must be paid with the submission of the application for issuing a Certificate of a Pharmaceutical Product. Please note that during the payment of the relevant fee via JCC, the applicant should always complete the appropriate fields with the product names for all products concerned and the date of application.
- Letter of Authorization from the Marketing Authorisation Holder (if the applicant is not the MAH).

3. As of **May 1st 2024**, **only** applications submitted electronically to the above email address will be accepted. Marketing authorisation holders or/and authorised local representatives should submit all of the above documents via a **single electronic submission** to the above email. Pharmaceutical Services will reply to the e-mail notifying the applicant with regards to the issuing or not of the Certificate or the necessity of further information and/or corrections. Furthermore, the applicant will be informed via email for the collection of the certificates by the responsible person (Ms Poly Philippou tel:22-608622).

Applicants are requested to submit the necessary documents well in advance, in order to ensure that Pharmaceutical Services will have at their disposal the necessary time for the evaluation of the submitted documents and the issuance of the certificates in due time.

It is also noted that certificates cannot be changed after issuance, and applicants should submit new applications, if required.

Please note that as of **May1st, 2024** any submissions not made electronically to the dedicated e-mail address, will not be considered valid.

For any additional information/clarifications, you can contact Ms Irene Pericleous (ipericleous@phs.moh.gov.cy , tel: 22608629)

(Irene Pericleous)

For Registrar Drugs Council

ΣΥΝΗΜΜΕΝΟ 1

ΚΥΠΡΙΑΚΗ ΔΗΜΟΚΡΑΤΙΑ
REPUBLIC OF CYPRUS

ΦΑΡΜΑΚΕΥΤΙΚΕΣ ΥΠΗΡΕΣΙΕΣ
ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ

PHARMACEUTICAL SERVICES
MINISTRY OF HEALTH

ΑΙΤΗΣΗ ΓΙΑ ΕΚΔΟΣΗ ΠΙΣΤΟΠΟΙΗΤΙΚΟΥ ΦΑΡΜΑΚΕΥΤΙΚΟΥ ΠΡΟΙΟΝΤΟΣ

[Περί Φαρμάκων Ανθρώπινης Χρήσης (Τέλη) Κανονισμοί του 2024, ΚΔΠ 132/2024]

Ημερομηνία _____

Έφορο Συμβουλίου Φαρμάκων
Φαρμακευτικές Υπηρεσίες
Υπουργείο Υγείας
Λευκωσία 1475, ΚΥΠΡΟΣ
Τηλ.: +357 22 608 622
email: cppsubmissions@phs.moh.gov.cy

Παρακαλώ όπως εκδοθούν το (τα) πιο κάτω πιστοποιητικά:

Α/Α	Αριθμός φακέλου	Αριθμός άδειας Κυκλοφορίας	Όνομα φαρμακευτικού προϊόντος

Με τιμή

Υπογραφή
Ονοματεπώνυμο
Διεύθυνση

Τηλ.
Email:

(Έντυπο Φ.Υ. 111)

ΣΥΝΗΜΜΕΝΟ 2

CERTIFICATE OF A PHARMACEUTICAL PRODUCT

This Certificate conforms to the format recommended by the World Health Organization (WHO). It establishes the status of the pharmaceutical product and of the applicant for the certificate by the national certifying authority in the country or within the jurisdiction of the regional certifying authority. It is for a single product only since the manufacturing arrangements and approved information for different dosage forms and different strengths can vary. (General instructions and explanatory notes are attached.)

No. of Certificate: _____

Certifying country or regional certifying authority: **CYPRUS**

Requesting country (countries) or regional authority (authorities):

1. Basic information

1.1 Name: (International Nonproprietary Name (INN)/generic/chemical name); brand name of the pharmaceutical product as it is declared in the marketing authorization certificate and used within the territory of the certifying authority and, if possible, the brand name for the foreign country as declared by the requester, (if different); and, the dosage form of the finished pharmaceutical product (FPP):

1.2. Composition: active pharmaceutical ingredient name(s) using if possible, INNs or national nonproprietary names,. Unit formulation (complete quantitative composition including all excipients)[1] :

1.3. Is this product authorized by the certifying authority to be marketed in the certifying country or within the jurisdiction of the certifying regional authority? <**Yes/No**>

1.3.1 Are there restrictions of the sale, distribution or administration of the product specified in the Marketing authorisation? <**Yes/No**> See attached information if Yes.

1.4. Is this product actually on the market in the certifying country or within the jurisdiction of the certifying regional authority? <**Yes/No/Unknown**>

Sections 2A and 2B below are mutually exclusive, therefore:

- If the answer to 1.3 above is yes, continue with section 2A and omit section 2B.
- If the answer to 1.3 above is no, omit section 2A and continue with section 2B

2. Information of Marketing Authorisation

2.A. Product that is authorised for marketing by the certifying authority:

2.A.1. Number of marketing authorization and date of issue. (Indicate, when applicable, if the marketing authorization is provisional and the marketing authorization pathway, e.g. abridged, etc):

2.A.2. Marketing authorization holder (name and address):

2.A.3. Status of marketing authorization holder: (one of the options of 3.1, if manufacturer, or specify the status as importer or any other):

2.A.4. Is a summary basis for approval appended?<**Yes/No**> See attached information if answer is Yes

2.A.5. Is the attached, officially approved product information complete and consistent with the marketing authorization (such as the Summary of Product Characteristics – SPC- or similar)? **<Yes/No/Not provided> See attached information if answer is Yes**

2.A.6. Name and address of applicant for the certificate as provided by the marketing authorization holder, if different::

2.A.7. Web-link to the product marketing authorization information (if available)

2.B. Product that is not authorized for marketing by the certifying authority.

2.B.1. Applicant for certificate (name and address):

2.B.2. Why is marketing authorization lacking? <Not required/Not requested/Under consideration/Refused/Withdrawal for commercial reasons/Withdrawal for sanitary reasons>

2.B.3. Reason provided by the applicant for not requesting registration.

a. The product has been developed exclusively for the treatment of conditions (e.g. tropical diseases – not endemic in the exporting country
b. The product has been reformulated - please specify:
c. Any other reason, please specify:

3. Information on manufacturing and inspections

3.1 List of name and address of the manufacturing site(s) and activities[2]:
a. manufacturing of all steps of the finished pharmaceutical product (FPP);
b. manufacturing the bulk finished product;
c. manufacturing of solvent and diluents;
d. quality control of the FPP;
e. batch release of the FPP;
f. primary packaging of the dosage form;
g. secondary packaging of the product;
h. other(s) (specify and list in new arrows).

Name of manufacturing site	Address	Activity

3.2. Does the certifying authority arrange for periodic inspection of the manufacturing site in which the FPP is produced? **Yes/No If not, proceed to question 4**

3.3. Periodicity of routine inspections: **1-3 years (according to risk)**

3.4. Has the manufacturer of the dosage form of the FPP been inspected? **Yes/No** . If Yes, when feasible, insert date of inspection(s)

3.5 Do the facilities and operations of the manufacturer of the FPP conform to good manufacturing practices (GMP) as recommended by WHO? **Yes**/No

3.6. It is recommended that for products approved, but not manufactured in the country of the certifying authority, the source of information that assures the GMP compliance of the manufacturer(es) is declared.

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product[3]: (yes/no)

If the answer is No, please explain:

Address of certifying authority:

PHARMACEUTICAL SERVICES – MINISTRY OF HEALTH
1475 NICOSIA - CYPRUS

Telephone number: **22608625**

Website: https://www.moh.gov.cy/moh/phs/phs.nsf/home_

Email address :
Name and job title of authorized person:

Signature:

Stamp and date:

Explanatory notes:

1. Details of quantitative composition are preferred but their provision is subject to the agreement of the marketing authorization holder.
2. The requirements for good practices in the manufacture and quality control of pharmaceutical products referred to in the certificate, are those included in the Thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series, No. 986, 2014, Annex 2 (WHO Good manufacturing practices for pharmaceutical products: main principles). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Good manufacturing Practices for biological products, WHO Technical Report Series, No. 996, 2016, Annex 3).
3. It is of particular importance when contractors are involved in the manufacture of the product. The applicant should supply the certifying authority with information in order to identify the contracting parties responsible for each stage of manufacture of the finished dosage form and the extent and nature of any controls exercised over each of these parties.