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Via Electronic mail

To: Marketing Authorisation Holders and Local Representatives

Subject: Legal Status of Pharmaceutical Products

With reference to the above, you are notified that a new Decree has been published with regard to the legal status of medicinal products. The Decree concerns medicinal products requiring a prescription for their dispensing pursuant to article 80(3) of the Medicinal Products for Human Use (Control of Quality, Supply and Prices) Law ..

The Decree as well as the relevant Table (Public Instrument ΚΔΠ 37/2023, publication date: 3/2/2023) are available through the Pharmaceutical Services' website at the following link:

https://www.moh.gov.cy/Moh/phs/phs.nsf/All/C8DAF0AAD80237D2C225897B003630F9/$file/%CE%9A%CE%94%CE%A0%2037%20%CF%84%CE%BF%CF%85%202023.pdf?OpenElement

Please note that with the new Decree the previous Decrees are repealed. The new Decree contains a revised Preamble and applies to all medicinal products for which a marketing authorisation has been issued and is valid in Cyprus.

Table lists all medicinal products for which **a prescription is required** for their dispensing and the **Annex** lists medicinal products for the dispensing of which **a prescription is not required**. The Table also includes medicinal products for which a prescription as controlled drugs according to the Narcotic Drugs and Psychotropic

Substances Law and the relevant Narcotic Drugs and Psychotropic Substances Regulations is required.
Medicinal products authorized via the Centralized Procedure in accordance with Regulation 726/2004, are dispensed in accordance with the provisions (with or without prescription) as laid down in their marketing authorization as issued by the European Commission. Information with regard to the legal status of centralized products for which Pharmaceutical Services have been notified of their launch in Cyprus, is available via the Pharmaceutical Services portal and are not included in the new Decree.

According to the Decree, the legal status of medicinal products in the Table prevails over the legal status indicated in the corresponding marketing authorization. Moreover, the compliance to the legal status of all medicinal products with the new Decree is **mandatory** and Marketing Authorization Holders **are required** to proceed with the submission of the relevant variations/notifications of marketing authorisations, where necessary, namely medicinal products whose legal status as indicated in the new Decree is not in accordance with the legal status of their current marketing authorization.

The procedure for the submission of variations/notifications and the requested documentation for the change of the legal status in order to comply with the Decree is laid down in Annex 1 of this circular.

Please note also the following:

α) the legal status of all authorized hospital packs of medicinal products is Prescription Type I (Prescription which may not be renewed).

b) for medicinal products with a legal status of Prescription Type II (. Prescription which may be renewed), the repetition possibility of the prescription in accordance with paragraph 6(2)(c)) of the Decree, is only applicable to package(s) of the product in accordance to the prescribed dosage and the recommended treatment duration.

Marketing Authorisation Holders have a period of 3 months from the date of this circular for the submission of the required variations in order to comply with the current Decree and a period until the end of 2023 for the exhaustion of any available stocks of the products on the market.

It is noted that the legal status of medicinal products is a condition of their marketing authorization and non-compliance with the Decree consists a violation of the legislation. The Drugs Council will be performing relevant compliance checks.

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The Table will be updated for any changes in the current listings and for the inclusion of new medicinal products. However, the legal status of all authorized medicinal products will be available via the Pharmaceutical Services website (eServices/ Drug search), at the following link:

https://www.phs.moh.gov.cy/drugsearch/SearchName.iface

Dr Helena Panagiotopoulou

Registrar Drugs Council

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Annex 1

Procedure for the submission of variations/notifications for the change of legal status in order to comply with the Amendment Decree Κ.Δ.Π. 37/2023

For changes of the type of prescription via which the product is administered i.e. prescription type I to prescription type II and vice versa the MAHs are not obliged to submit a variation. The relevant changes will be made in the Pharmaceutical Services database and the MAHs are obliged to conform without any further regulatory actions.

For changes of the legal status from administration with prescription (type I or II) to administration without prescription and vice versa, variations should be submitted according to the below procedure:

- Products licensed through national, MRP, DCP procedure:

Requirement for the submission of relevant variation:

Type of variation: Type IB unforeseen

Classification: **C.I.5.z**.

Please note that this variation classification applies **only** in cases of requested compliance with the Decree. **For any other changes in the legal status of the medicinal product the variation guideline should be followed i.e. when the MAH would like to request a different legal status to the one stated in the Decree, the relevant variation according to the variation classification guideline should be submitted.**

Grouped Variations: Acceptable only for different strengths and or different pharmaceutical forms of the same product.

Implementation date: Upon completion of the assessment and receipt of a variation approval.

Requested documentation for variation purposes:

1. Signed Cover letter
2. Signed Application Form fully completed

3. Updated PIL & Labelling and SmPC where applicable (working documents – clean version & track changes version)
4. Mock-ups [secondary packaging & (primary packaging if applicable)] of all pack sizes registered (at least all pack sizes marketed in Cyprus).

All variations should be submitted via CESP.

- Parallel import products and Exceptional Marketing Authorisations (article 13A) :

Requirement for the submission of relevant notification:

Implementation date: Upon completion of the assessment and receipt of a notification/acceptance letter.

Requested documentation for notification purposes:

1. Signed Cover letter
2. Updated PIL (working documents – clean version & track changes version) if applicable
3. Mock-ups [secondary packaging & (primary packaging if applicable)] of all pack sizes marketed in Cyprus

All notifications should be submitted via CESP.

With regards to products for which there is a different legal status for different approved pack sizes within one marketing authorization, the patient leaflet and labeling for both OTC and Rx pack sizes will be handled as follows:

Additional Note:
Information concerning medicinal products not subject to medical prescription should always be in gray-shading, however information concerning medicinal products subject to medical prescription should not be in gray shading.
The printing of the appropriate version of the Patient Information Leaflet should be made according to the pack sizes. See examples below:

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Patient Leaflet

Only 1 Patient Information Leaflet should be submitted containing the following information

<**Read all of this leaflet carefully before you start <taking> <using> this medicine because it contains important information for you.**

Always <take> <use> this medicine exactly as described in this leaflet or as your <doctor> <,> <or> <pharmacist> <or nurse> <has> <have> told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your <doctor> <,> <or> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse <after {number of} days.>>

<**Read all of this leaflet carefully before you start <taking> <using> this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your <doctor> <,> <or> <pharmacist> <or nurse>.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.>
- If you get any side effects, talk to your <doctor> <,> <or> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. See section 4.>

Section 6 of the Patient Information Leaflet

Pack sizes: 10 and 20 tablets

Not all pack sizes may be marketed.

Pack sizes: 10, 20, 30, 60 and 100 tablets

Pack sizes not subject to medical prescription: 10 and 20 tablets
Pack sizes subject to medical prescription: 30, 60 and 100 tablets

Not all pack sizes may be marketed.

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Labelling

Only 1 Labelling should be submitted containing the following information

14. GENERAL CLASSIFICATION FOR SUPPLY

For pack sizes of 10 and 20 tablets
Medicinal product not subject to medical prescription

For pack sizes of 30, 60 and 100 tablets
Medicinal product subject to medical prescription

15. INSTRUCTIONS ON USE

For pack sizes of 10 and 20 tablets
- Indication(s).
- Dose recommendations, contraindication(s) and warnings; if full details cannot be printed, a reference to the package leaflet should be made, e.g. “Read the package leaflet before use”.

17. UNIQUE IDENTIFIER – 2D BARCODE

For pack sizes of 10 and 20 tablets
<Not applicable.>

For pack sizes of 30, 60 and 100 tablets
<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

For pack sizes of 10 and 20 tablets
<Not applicable.>
For pack sizes of 30, 60 and 100 tablets
< PC {number} [product code]
SN {number} [serial number]
NN {number} [national reimbursement number or other national number identifying the medicinal product]>