**PHARMACY AND POISONS BOARD**
**HONG KONG**
**香港藥劑業及毒藥管理局**

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圖文傳真

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**20樓2002-05室**

15th December 2020

To: Certificate holders of
registered pharmaceutical products

Dear Sir / Madam,

**New Warnings for Products containing Cyproterone**

On 7th December 2020, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) considered the latest new warnings to restrict the use of cyproterone due to meningioma risk imposed by the drug regulatory authorities of the European Union, the United Kingdom, Canada, Australia and Singapore, and decided that the sales pack labels and / or package inserts of such registered products should be updated to include the following new safety information as appropriate:

(I) **For combination products containing cyproterone and ethinylestradiol or estradiol valerate:**

*(i) Under "Contraindications":*

*Meningioma or history of meningioma*

*(ii) Under "Special warnings and precautions for use":*

*Meningioma: The occurrence of meningiomas (single and multiple) has been reported in association with use of cyproterone acetate, especially at high doses of 25 mg and above and for prolonged time. If a patient is diagnosed with meningioma, any cyproterone containing treatment, including <Product name>, must be stopped, as a precautionary measure.*

(II) **For products containing cyproterone 10mg or above:**

*(i) Under "Indications":*

*For products indicated for use in women (severe signs of androgenisation in the woman, e.g. hirsutism, androgenetic alopecia or acne and seborrhoea) dosed at 10 mg or 50mg, the following wording should be added after the indication:*
*For <indication(s)>, cyproterone acetate <10 mg/50mg> is indicated when no satisfactory results have been achieved with lower dose cyproterone-containing products or with other treatment options.*

*For products indicated for reduction of sexual deviations in adult males dosed at 50mg, 100 mg or 300 mg/3 ml, the following should be added after the wording of the indication:*
*For reduction of drive in sexual deviations in men, cyproterone acetate <50 mg/100 mg/300 mg/3 ml> can be used when other interventions are considered inappropriate.*

*(ii) Under "Posology":*

*For products authorised for use in women (severe signs of androgenisation in the woman, e.g. hirsutism, androgenetic alopecia or acne and seborrhoea) dosed at 10 mg, the following wording should be added/revised after the posology:*
*After clinical improvement, the lowest effective dose should be used, which may include cyproterone acetate 2 mg/ethinylestradiol 35 mcg.*

*For products authorised for reduction of sexual deviations in adult males dosed at 50mg, 100 mg or 300 mg/3 ml, the following should be added/adapted after the posology:*
*The duration of cyproterone acetate treatment should be defined on an individual basis. When a satisfactory result has been achieved,*

*the therapeutic effect should be maintained with the lowest possible dose. When changing the dose or when discontinuing cyproterone acetate, this should be done gradually.*

(iii) *Under "Contraindications":*

*Meningioma or history of meningioma*

(iv) *Under "Special warnings and precautions for use":*

*Meningioma: The occurrence of meningiomas (single and multiple) has been reported in association with use of cyproterone acetate primarily at doses of 25 mg and above. The risk of meningioma increases with increasing cumulative doses of cyproterone acetate. High cumulative doses can be reached with prolonged use (several years) or shorter duration with high daily doses. Patients should be monitored for meningiomas in accordance with clinical practice. If a patient treated with <Product Name> is diagnosed with meningioma, treatment with <Product Name> and other cyproterone containing products must be permanently stopped. There is some evidence that the meningioma risk may decrease after treatment discontinuation of cyproterone.*

(v) *Under "Undesirable effects":*

*Meningioma – frequency rare.*
*The occurrence of meningiomas (single and multiple) has been reported in association with use of cyproterone acetate.*

You are therefore required to review and revise, if necessary, the sales pack labels and / or package inserts of the concerned products registered by your company to ensure that the products comply with the above new requirements. The revised sales pack labels and / or package inserts should be submitted to the Committee for approval within 2 months from the date of this letter. Failing to comply with the above requirements may result in de-registration of the products or registration not renewed by the Committee.

If you have any enquiries on the above issue, please contact Ms. Queenie CHAN at 3974 4147.

Yours faithfully,

(T.K. YIM)
Secretary,
Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee

c.c. 7-15/3, Product Files

TK/QC