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

Your Ref. :
貴處檔號

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圖文傳真

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12th December 2017

To: Certificate holders of
registered pharmaceutical products

Dear Sir / Madam,

New Warnings for Codeine, Dihydrocodeine and Tramadol

On 7th December 2017, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) considered the latest warnings for oral preparations containing codeine, dihydrocodeine and tramadol imposed by the drug regulatory authorities of the United States, European Union, United Kingdom, Australia, Canada and Singapore, and decided that the sales pack labels and/or package inserts of registered pharmaceutical products containing codeine, dihydrocodeine and tramadol should include the following new information:

For pharmaceutical products containing codeine:

(i) To replace the existing safety information "Codeine is not recommended for use in children less than 12 years of age." with the following contraindication:

"Codeine is contraindicated for all children younger than 12 years of age."

(ii) To replace the existing safety information "Codeine should not be used at all in children (aged below 18 years) who undergo surgery for the removal of the tonsils or adenoids to treat obstructive sleep apnoea." with the following contraindication:

"Codeine is contraindicated for post-operative management in children younger than 18 years of age following tonsillectomy and/or adenoidectomy."

(iii) To replace the existing safety information "Codeine should not be used in children with conditions associated with breathing problems." with the following warning:

"Avoid the use of codeine in adolescents 12 to 18 years of age who have other risk factors that may increase their sensitivity to the respiratory depressant effects of codeine unless the benefits outweigh the risks. Risk factors include conditions associated with hypoventilation, such as postoperative status, obstructive sleep apnea, obesity, severe pulmonary disease, neuromuscular disease, and concomitant use of other medications that cause respiratory depression."

(iv) To modify the existing statement "Codeine should not be used in people of any age who are known to be ultra-rapid metabolisers nor in breastfeeding mothers." with the following safety information:

"Codeine should not be used in people of any age who are known to be ultra-rapid metabolisers."

AND

"Because of the potential for serious adverse reactions, including excess sedation, respiratory depression, and death in a breastfed infant, breastfeeding is not recommended during treatment with codeine."

For pharmaceutical products containing dihydrocodeine:

Contraindications
[Product Name] is contraindicated for:
- *All children younger than 12 years of age.*

- *Post-operative management in children younger than 18 years of age following tonsillectomy and/or adenoidectomy.*

Warnings and Precautions
Avoid the use of [Product Name] in adolescents 12 to 18 years of age who have other risk factors that may increase their sensitivity to the respiratory depressant effects of dihydrocodeine unless the benefits outweigh the risks. Risk factors include conditions associated with hypoventilation, such as postoperative status, obstructive sleep apnea, obesity, severe pulmonary disease, neuromuscular disease, and concomitant use of other medications that cause respiratory depression.

Lactation
Because of the potential for serious adverse reactions, including excess sedation, respiratory depression, and death in a breastfed infant, breastfeeding is not recommended during treatment with [Product Name].

For pharmaceutical products containing tramadol:

Contraindications
[Product Name] is contraindicated for:
- *All children younger than 12 years of age.*
- *Post-operative management in children younger than 18 years of age following tonsillectomy and/or adenoidectomy.*

Warnings and Precautions
Avoid the use of [Product Name] in adolescents 12 to 18 years of age who have other risk factors that may increase their sensitivity to the respiratory depressant effects of tramadol unless the benefits outweigh the risks. Risk factors include conditions associated with hypoventilation, such as postoperative status, obstructive sleep apnea, obesity, severe pulmonary disease, neuromuscular disease, and concomitant use of other medications that cause respiratory depression.

Lactation
Because of the potential for serious adverse reactions, including excess sedation and respiratory depression in a breastfed infant, breastfeeding is not recommended during treatment with [Product Name].

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 by the Committee.

If you have any enquiries on the above issue, please contact Mr. Paul Wong at 2209 9495.

Yours faithfully,

(TK 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/PW