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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本局檔號

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圖文傳真

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公共衛生檢測中心三樓

24th February 2017

To: Certificate holders of
registered pharmaceutical products

Dear Sirs / Madams,

New Recommendations for Metformin

On 23rd February 2017, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) considered the latest overseas recommendations on the use of metformin, and decided that the sales pack labels and/or package inserts of registered pharmaceutical products containing metformin should include the following new information:

Posology on Renal Impairment:

A GFR should be assessed before initiation of treatment with metformin containing products and at least annually thereafter. In patients at an increased risk of further progression of renal impairment and in the elderly, renal function should be assessed more frequently, e.g. every 3-6 months.

For products containing metformin as single agent and for fixed dose combination products containing metformin:

GFR mL/min	*Total maximum daily dose (to be preferably divided into 2-3 daily doses)*	*Additional considerations*
60-89	*3000 mg*	*Dose reduction may be considered in relation to declining renal function.*
45-59	*2000 mg*	*Factors that may increase the risk of lactic acidosis should be reviewed before considering initiation of metformin. The starting dose is at most half of the maximum dose.*
30-44	*1000mg*	
<30	*-*	*Metformin is contraindicated.*

For extended-release products containing metformin as single agent:

GFR mL/min	*Total maximum daily dose*	*Additional considerations*
60-89	*2000 mg*	*Dose reduction may be considered in relation to declining renal function.*
45-59	*2000 mg*	*Factors that may increase the risk of lactic acidosis should be reviewed before considering initiation of metformin. The starting dose is at most half of the maximum dose.*
30-44	*1000mg*	
<30	*-*	*Metformin is contraindicated.*

Special Warnings

Intravascular administration of iodinated contrast agents may lead to contrast induced nephropathy, resulting in metformin accumulation and an increased risk of lactic acidosis. Metformin should be discontinued prior to or at the time of the imaging procedure and not restarted until at least 48 hours after, provided that renal function has been re-evaluated and found to be stable.

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 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 Arthur Lee at 2319 8453.

Yours sincerely,

(Clive CHAN)
Secretary,
Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee

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

CC/ART