Dear Healthcare Professionals,

**Oral lidocaine-containing products for infant teething: only to be available under the supervision of a pharmacist in the United Kingdom**

Your attention is drawn to the Medicines and Healthcare products Regulatory Agency’s (MHRA) announcement that oral lidocaine-containing products for infant teething are only to be available under the supervision of a pharmacist so that parents and caregivers can receive guidance about managing infant teething symptoms. Non-medicinal options such as a teething ring or massaging the gum should be the first line for relieving infant teething symptoms, and lidocaine-containing products should only be used when simple measures have failed to provide sufficient relief. Sugar-free paracetamol or ibuprofen suspensions, administered according to the approved indication and dose for weight and age, can also be considered for the relief of teething symptoms.

The Commission on Human Medicines (CHM) has advised on measures to improve the safe use of lidocaine-containing products for teething in children. In an in-depth review of the benefits and risks of these products, CHM identified a number of reports of medication error received via the Yellow Card Scheme. Most reports did not include an associated adverse event and were not thought to result in harm, but the committee recommended that the administration instructions should be improved and harmonised to ensure parents and caregivers received consistent advice on the safe use of these medicines in babies. CHM recommended that pharmacists were best placed to provide guidance to parents and caregivers on options for teething symptoms, including when symptoms could suggest more serious conditions that need medical assessment.

The legal status of newly manufactured stock of oral lidocaine-containing products indicated for infant teething is changing from general sale (GSL) to pharmacy (P). This change means that oral lidocaine products for infant teething can only be sold in pharmacies where advice can be given by the pharmacist.

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Instructions for administration and safety warnings are being updated in the new patient information leaflet. Advice is being given to parents and caregivers to seek medical attention if their child’s condition does not improve and not to use more than one product containing lidocaine at the same time.

Oral lidocaine products that are approved in adults or in other conditions (eg, mouth ulcers) will remain GSL but should not be used in infants for teething because they have different approved dosing regimens. The patient information leaflets and cartons of these oral lidocaine-containing products without a teething indication are being updated accordingly.

Please refer to the following website in MHRA for details:

In Hong Kong, there are 48 registered pharmaceutical products containing lignocaine for dental/oromucosal applications. So far, the Department of Health (DH) has not received any case of adverse drug reaction related to these products. News related to the safety of lignocaine viscous products in infants and children was previously issued by the US Food and Drug Administration, and was posted on the Drug Office website on 27 Jun 2014. In Feb 2015, the Registration Committee of the Pharmacy and Poisons Board decided that topical oral lignocaine products (for strength >=2%) should not be used to treat infants and children with teething pain. In light of the above MHRA's announcement on the update of patient information of oral lignocaine products, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under “ADR Reporting”: http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

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for Assistant Director (Drug)

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