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Date 2008-04-07

Our ref HANX

Your ref -

Position from H. Lundbeck A/S on Legal proposal on Information to patients

Dear Colleagues,

H. Lundbeck A/S welcomes this legal proposal on Information to patients. Furthermore we welcome the opportunity to comment.

Regarding section 3.2 and the criterions to distinguish information that is allowed and information that is not allowed: In this respect it is essential that it is allowed for the manufacturers of medicines to put a statement on the packages that verification of authenticity is possible and referring to an email address, a phone number and preferably even a web site without this being regarded as advertisement. To allow this kind of information would enable the industry to use web-based technologies to fight counterfeit and allow an easy verification of the authenticity of the product. Furthermore this will help protect patient safety as an effort to appropriately communicate useful information to patients.

Kind regards,

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Dr. Iman Barilero, Pharm D, MSc, PhD Divisional Director Regulatory Development Strategy

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