To the attention of the Press :

March 11, 2011

Sanofi Pasteur KK
Daiichi Sankyo Co., Ltd.

Voluntary recall of hemophilus influenza type b conjugate vaccine "ActHIB®"

Sanofi Pasteur KK (Head Office: Shinjuku-ku, Tokyo; Representative Director and President: Franck Perraudin, hereinafter "Sanofi Pasteur") and Daiichi Sankyo Co., Ltd. (Head Office: Chuo-ku, Tokyo; Representative Director and President and CEO: Joji Nakayama, hereinafter "Daiichi Sankyo") have decided to voluntarily recall part of the products "ActHIB®" (generic name: hemophilus influenza type b conjugate vaccine) which are manufactured and marketed by Sanofi Pasteur and distributed by Daiichi Sankyo. This voluntary recall of some ActHIB products is due to a notification of contamination by foreign matter and the resulting investigation which confirmed two cases of contamination inside syringes of diluent which are used to reconstitute ActHIB.

As a result of analysis of information by Sanofi Pasteur up to the present time, it has been confirmed that the foreign matter was aseptic (nonbacterial). However, in order to eliminate every possible risk, it was decided to voluntarily recall the ActHIB products which were manufactured in the same manufacturing process as the syringes in which the foreign matter was confirmed starting today.

Please allow us to express our sincere apologies for the inconveniences and concern this recall may cause to health professionals and families of infants eligible for immunization with "ActHIB®." Sanofi Pasteur will endeavor to find the cause of this matter and prevent recurrences of the incidence by reviewing quality measures at the production stage. Your understanding of the present voluntary recall would be much appreciated.

Lot numbers of products subject to recall:

E0771	E1174	E0962	E1065	E1235	E1201	G1030
E0897	E1200	E1033	E1160	E1236	G1018	

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Inquiries:

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