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cc: Professor Markku Pasanen, University of Kuopio, Finland

Helsinki, June 4, 2013

Dear Dr Peter Arlett,

We would like to inform you personally of the suspected serious reactions related to Synflorix® - vaccine, the effectiveness of which has been studied in a clinical trial conducted in Finland between years 2009 and 2010. The results of this FinIP-trial trial have been published last autumn in the Lancet (**http://www.thl.fi/thl-client/pdfs/b4e58de5-8b48-4504-8e92-0318fba6dfbc**).

The major issue here is that the serious adverse reactions experienced by the study subjects (and later on by the children vaccinated according to our national vaccination program) have not been reported by the physicians or by the nurses to the regulators (at FIMEA or National Institute for Health and Welfare or THL). This misconduct is most likely due to the passive follow-up method (i.e. based on spontaneous reporting) used in the clinical FinIP-trial and in normal clinical routine since then.

This issue has been brought up by the parents, whose children have fallen seriously ill after vaccination and by the homeopaths taking care of those kids.

Recently, our volunteer team (including surgeon, GP, nurse and undersigned) have informed the FIMEA and THL of the following serious adverse reactions:

- Two cases leading to permanent disabilities
- One fatal outcome (unconfirmed report from the Finnish newspaper)
- Two cases with persistent untypical epileptic seizures
- One case of extended infections followed by persistent nightmares, screaming episodes and general weakness
- Three cases of continuous infections including serious infections requiring in-patient hospitalization

All these children had been healthy before the vaccination(s) and their throughful medical examinations conducted at Finnish University Hospitals have not revealed any identifiable reason for the significant health deterioration. After a careful evaluation of the medical records, our understanding is that the causality between Synflorix® vaccination (possibly as a clinically significant interaction with concomitantly given Infarix® vaccine) and serious adverse reactions is probable or at least possible. The details of these cases are described in the attached documents, which have been sent to the Parliamentary Ombudsman and which, therefore, unfortunately are available only in Finnish language.

Our suspicion is further supported by the fact that our two cases leading to the permanent disabilities are very similar with the 70 cases described in Infarix hexa™ Summary Bridging Report 16 December 2011 (http://ddata.over-blog.com/3/27/09/71/2012-2013/confid.pdf). 'Gaze palsy' has been a leading symptom in all of these cases. We received this report incidentally from the social media and realized that in almost 50 out of 70 cases the child had received concomitantly Infarix hexa™ and pneumococcal vaccine. This finding raises the important question of a potentially serious interaction between pneumococcal vaccines and Infarix® or Infarix hexa™ vaccines.

The overall number of our suspected cases is about 20, but we have reported to the regulators only those eight cases from whom the medical records have been available for our review. We would like to emphasize that all this research has been conducted on a volunteer basis, and that we have been totally dependent on parents' possibilities to provide us with all the necessary medical information. Due to the remarkable practical difficulties in collecting all the necessary data in this kind of an unofficial way, we wish that our efforts describing these few 'ice berg' cases would trigger further evaluations at regulatory site.

We decided to approach you directly hoping to fasten the possible initiation of the official evaluations, which we feel would be necessary based on our best current knowledge. Unfortunately, it is beyond our reasonable possibilities to translate into English language all the documents that we have written in Finnish for the national purposes. Maybe, some Finnish workers at EMA could help you with the translations as suggested by Professor Markku Pasanen (member of Scientific Advise Working Party, SAWP) with whom I have discussed of our serious concerns.

On behalf of our volunteer expert group incl. Dr. Taija Somppi (a surgeon), Dr. Liisa Sulkakoski (a GP) and Mrs. Merja Lindström (a homeopathic nurse)

Sincerely,

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Attachments: Clarification request (in Finnish) given to the Parliament Ombudsman on May 30, 2013