



**Initiative Citoyenne**  
Liberté vaccinale- information

Initiative Citoyenne Press Release

**Confidential Documents on the Prevenar 13 Vaccine: Proof that BOTH the Manufacturers AND the Health Authorities KNOW why we are Concerned!**

On the 8<sup>th</sup> of December, articles in the press reported on the contents of a substantial 1,271-page confidential GSK document<sup>1</sup> leaked to us by contacts at the Belgian Medicines Agency. This shocking document on the pharmacovigilance of the Infanrix Hexa vaccine revealed serious safety problems evidenced by a whole range of serious complications, including 36 deaths (over a 2-year period). None of this information had ever been communicated to parents, representing a clear breach of Belgian law of the 22<sup>nd</sup> August 2002 on patient information.

We have now received more confidential documents on the safety of another paediatric vaccine very commonly used on infants and administered alongside the Infanrix Hexa hexavalent vaccine: **the Prevenar 13, a pneumococcal vaccine manufactured by Wyeth/Pfizer.**

This is an injection targetting 13 different strains of the bacterium and reputed to be an improved version of the old Prevenar (targeting only 7 strains). It was in fact rushed to market in 2010 to replace the older vaccine, presumably an attempt to cover up the fiasco of its predecessor: the original Prevenar had disappointingly resulted in an increase in serious infections making it totally counterproductive.<sup>2</sup>

OK, so the vaccine is not as effective as they tell us but is it at least safe for such tiny babies?

It would appear, according to recent confidential Wyeth (Pfizer) documents and to a reply from the European Medicines Agency (EMA) that **both the manufacturer and the agency are aware of a significantly higher number of adverse neurologic effects in children vaccinated with BOTH Prevenar 13 AND Infanrix Hexa, as per the Belgian vaccination schedule at ages 2 and 4 months.**

On the 4<sup>th</sup> of January this year, at the end of the required 6-week period, two Pfizer group Regulatory Affairs Directors, Mary Allin and Helen Edwards, sent a response to Dr. S. Spinosa of the European Medicine Agency on the topic of “**higher number of neurologic events reported in Italy following the co-administration of Prevenar 13 and hexavalent vaccines**”. The two directors specified at the end of this letter that based on data supplied, they did not feel there was any need to modify the vaccine’s reference safety information (RSI), in other words its package insert.<sup>3</sup>

At the same time, another confidential document, nothing more than **correspondence between a division of the European Medicines Agency (Committee for Medicinal Products for Human Use or CHMP) and Pfizer (MAH)**<sup>4</sup>, specifies that “**the risk/benefit profile of the Prevenar 13 remains positive but the following potential safety concerns required further investigation/discussion by the MAH:**

1) **Deaths.** There were 22 fatal cases during the reporting period which represents 2.6% of the total number of cases. This proportion has increased from 0.3% during the previous reporting period. Additionally, in a large majority of these cases, the time interval between receipt of 13vPnC and death (or onset of symptomatology leading to death) is narrow. The case presentations of the fatal cases is considered inadequate.

2) **Lack of efficacy.** There were 51 cases reported for lack of efficacy. The MAH notes that it currently uses only 3 MedDRA preferred terms (vaccination failure, therapeutic product effective, and drug ineffective) to capture these reports. There is a concern that cases of reported events of pneumococcal disease, without concomitant coding of one of these three terms are “missed”: at least 10 case numbers were identified by this Assessor from the Infections and infestations SOC which exemplified this concern. Additionally, the large majority of reports

relating to “lack of efficacy” appear to report only 3 serotypes: 19A, 3 and 7. The MAH is request to comment upon this.

**4) Neurological events in subjects receiving Prevenar 13 concomitantly with hexavalent vaccines.** Following a inquiry at the October Pharmacovigilance Working Party regarding a potential increase in the incidence of neurological reactions with coadministered vaccines noted in a national vaccination program in IT, the MAH is requested to provide a cumulative review of neurological reactions in those cases who were reported to have received Prevenar 13 concomitantly with hexavalent vaccine

We then have the response of the producer which had delved into a Pfizer database covering the 2-year period from the 10<sup>th</sup> of July 2009 to the 9<sup>th</sup> of July 2011.

The manufacturer informs us that over this period, Pfizer received **1,691** reports of adverse events and **18% of these cases, i.e. 312 events, were neurological.**

An important fact is that Pfizer assessed **the respective frequency of neurologic accidents in three different groups of children: those who had all received only the Prevenar 13 on the same day, those who had received both the Prevenar 13 and other vaccines on the same day and those who had received both the Prevenar 13 and a hexavalent vaccine on the same day.**

Of the 934 children who had only received the Prevenar 13 and experienced adverse effects, 87 displayed neurologic events (87/934 = **9%**).

Of the 287 children who had received the Prevenar 13 plus other vaccines on the same day, and experienced adverse effects, 62 had had neurologic episodes (62/287 = **21%**).

Of the 470 children who received the Prevenar 13 plus a hexavalent vaccine, on the same day, and reported adverse effects, 163 had experienced neurologic reactions (163/470 = **34%!!**).

It is therefore clear that the concomitant administration of several vaccines, particularly those recommended in the Belgian vaccine schedule (Prevenar 13 alongside Infanrix Hexa), multiplies the risk of neurologic reactions including serious and potentially irreversible adverse events! This is precisely what we have been saying for years regarding the dangerous over-vaccination of infants.

Whether persistent crying, convulsions, hypotonic-hyporesponsive episodes, tremors, **loss of consciousness**, epilepsy, infantile spasms or absence of response to stimuli, these effects were always more frequent when the Prevenar 13 was administered alongside the Infanrix Hexa. So how many parents were aware of this and who told them? Did the Belgian Office for Childbirth and Childhood (ONE) tell them?

The ONE has always claimed in all its literature that the co-administration of several vaccines was totally safe, that any adverse effects were in general similar to those experienced with the administration of these vaccines separately<sup>5</sup> and even that concomitant administration of these vaccines reduced the ‘discomfort for the child’. Their overall commitment to vaccines has never waned!<sup>6</sup>

We also notice that both the European Medicines Agency has highlighted, as have we, using the confidential document on Infanrix Hexa, **the clear temporal relationship in most of these cases between the vaccination and death as well as between the vaccination and the various neurologic complications reported such as convulsions and hypotonia** (most of which took place within 24 hours of the vaccination or shortly thereafter)<sup>7</sup>.

Lastly, a third very important confidential document on the Prevenar 13 provides condemning clinical trial data.<sup>8</sup> This document states that on the 2<sup>nd</sup> of December 2008, the manufacturer requested authorization to register and market its Prevenar 13 vaccine across Europe and authorization was granted on the 9th of December 2009. These data were then used to authorize the vaccine for use in both Japan and Canada as well. When however it comes to product tolerance, the information is quite shocking.

First of all, the most incredible is **the methodology and the number of children monitored to assess the “safety” of the Prevenar 13:** instead of comparing a large sample of vaccinated children with another group of totally unvaccinated children, the manufacturer compared his Prevenar 13 (i.e. the new version) with its predecessor (Prevenar 7)!!

And when it comes to the number of children assessed, it is ridiculously low: 796 babies + 569 young children = a total of 1,365 children, spread over two studies and four groups (Prevenar 13/Prevenar 7 given to babies or young children depending on the study) while 10,000 children is sometimes still considered insufficient to assess the rare serious adverse effects! The adverse effects were monitored for six months in only 580 cases. Several children were even 'conveniently' withdrawn from these data because the manufacturer decided, arbitrarily, that their adverse effects were in no way linked to the vaccine being assessed!

We also learn that first of all **the frequency of both local and systemic adverse effects is significantly higher when the injection is intramuscular compared with sub-cutaneous** (in spite of this, the package insert still advises intramuscular injection!).

To grasp the proportions here, it is important to know that sensitivity at the site of injection is 13 to 20% in those vaccinated sub-cutaneously compared with 72 to 79% in those who receive an intramuscular injection.

The figures are even more revealing when it comes to the systemic effects:

**Less than 8.1%** of children receiving a sub-cutaneous jab had to take fever-reducing medication after the vaccination compared with between **78 and 84%** of those who were given an intramuscular injection! **Loss of appetite** occurred in less than 19% of those receiving a sub-cutaneous inoculation compared with over 54% in those for whom the jab was intramuscular. Irritability arose in less than 37% of the former while it was over 88% in the latter, drowsiness in less than 41% of the former compared with over 70% in the latter and disturbed sleep in less than 24% of the former while it was over 45% in the latter.

**Not surprisingly, these data reveal clearly that a deeper injection of the toxic substances in a vaccine (including neurotoxic aluminium) into the tissues of the body presents much greater risk. According to the research team at the Henri Mondor University Hospital in Créteil, France, the aluminium administered by intramuscular rather than sub-cutaneous injection is without a shadow of a doubt a major contributing factor in the emergence of cases of macrophagic myofasciitis (MMF).<sup>9</sup>**

This confidential document on clinical trials specifies however that regardless of the method of administration (sub-cutaneous or intramuscular), **83 to 92% of the recipients spontaneously reported adverse effects**, a bit of a shock when assessing products designed for healthy people!

As for SERIOUS adverse effects and their incidence in the clinical trials, the manufacturer informs us that in one study, no fewer than 30 serious reactions were observed in 22 individuals **which is an 11.4% rate of serious adverse events!! Most of these reactions were infections and conditions requiring hospitalisation. The manufacturer was however quick to point out that according to the rapporteur, NONE of these serious reactions was deemed to be linked to the vaccination!!**

What is more, this rate was considerably higher in babies than in slightly older children, confirming that the immaturity of a baby's immune system is not at all compatible with the vaccination drive now recommended by experts blinded by conflicts of interest.

**A total of 42 out of the 1,365 individuals assessed displayed serious adverse effects, i.e. 3%, a totally unacceptable rate which is clearly higher than the incidence of serious complications from pneumococcal disease in the general population!!**

To grasp the **extent of the problem**, just remember that the Belgian annual birth rate is approximately 128,000, a very large majority of whom receive BOTH the Prevenar and the Infanrix Hexa. A simple calculation reveals therefore that the annual number of serious adverse effects, taking ONLY this vaccine into account, could be 3% x 128,000 births = **3,840 children!!!!**

**In conclusion, these data are not very reassuring and it is clear that the health authorities are hiding far too much information which could be extremely USEFUL to parents who are expected to act in the interest of their children. Serious adverse effects are much more frequent than they claim and the health of our children is being DIRECTLY jeopardised first by this commitment to ideology but also by the rigid vaccination schedule recommendations which push a maximum of concomitant doses, to obtain parental compliance: yes, but above all to protect the commercial interests at stake!**

*Initiative Citoyenne* is therefore issuing a bold call to arms against the blind and unbridled pursuit of these death-dealing policies so detrimental to public health. We call upon all **honest and willing** members of the public to demand an end to this ‘Code of Silence’, this taboo, but also to the blind ideology which reigns over the current vaccination drive.

Our infants and children are literally overpowered by the current number of vaccines they are given but what can they do? They are simply SPEECHLESS.

On behalf of *Initiative Citoyenne*

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<http://www.initiativecitoyenne.be>

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<sup>1</sup> <http://ddata.over-blog.com/3/27/09/71/2012-2013/confid.pdf>

<sup>2</sup> <http://www.initiativecitoyenne.be/article-pneumocoques-l-echec-retentissant-de-la-vaccination-86420861.html>

<sup>3</sup> <http://ddata.over-blog.com/3/27/09/71/2012-2013/Wyeth-confidential-neurological-events.pdf>

<sup>4</sup> <http://ddata.over-blog.com/3/27/09/71/2012-2013/emea-responses--Prevenar-13-Pfizer-Confidential.pdf>

<sup>5</sup> <http://ddata.over-blog.com/xxxyyy/3/27/09/71/dec-2011/ONE-p.-225.pdf>

<sup>6</sup> <http://www.sante.cfwb.be/index.php?id=programme>

<sup>7</sup> <http://ddata.over-blog.com/3/27/09/71/2012-2013/emea-responses--Prevenar-13-Pfizer-Confidential.pdf> (cf p. 2, 7 and 10/12)

<sup>8</sup> <http://ddata.over-blog.com/3/27/09/71/2012-2013/Prevenar--confidential--overview-clinical-trials.pdf>

<sup>9</sup> [http://www.kine-formations.com/docs/Myofasciite\\_a\\_macrophages.pdf](http://www.kine-formations.com/docs/Myofasciite_a_macrophages.pdf) (cf p. 18 and 20 of the pdf)