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Initiative Citoyenne
Liberté vaccinale- information

Initiative Citoyenne Press Release

Safety of the Infanrix Hexa Vaccine: Confidential Document from GSK to the Authorities

We seem to have acquired a 1,271-page **confidential** GSK document, ordinarily reserved for the authorities. Topic: the pharmacovigilance of the Infanrix Hexa (6-in-1) paediatric vaccine. (1)

The Infanrix Hexa vaccine is a "free" inoculation administered to almost all the infants in Belgium, mainly through the ONE (*Office de la Naissance et de l'Enfance* = Office for Childbirth and Childhood) but also through paediatricians and general practitioners. It is intended to protect newborns and infants from six different illnesses: Diphtheria, Tetanus, Whooping Cough, Polio, Haemophilius Influenza B (HIB) and Hepatitis B.

The document in question details the adverse effects of this vaccine, reported back to the manufacturer from various European countries between the 23rd of October 2009 and the 22nd of October 2011. We can understand why it is confidential: no less than **825 different types of complication and adverse effect** are mentioned.

It is important, first of all, to point out that **the list covers a very broad range of adverse effects potentially involving each and every system and organ in the body**: the blood, the cardiovascular system, the nervous system, the immune system, the lungs, the skin but also the sensory organs (sight, hearing…), the musculoskeletal system, the joints, the urinary system, the digestive system and the endocrine system.

During this specific period of time, GSK received **1,742 reports of adverse effects**, of which **503** were serious effects not listed and **56** were serious adverse effects listed. The events registered included **36 deaths** (over the two-years period), most of which occurred within three days after the child received the Infanrix Hexa vaccine.

According to GSK, the adverse effect notification rate was 14.6 per 100,000 doses distributed but don't forget that the number of doses actually used/administered is always lower than the number of doses distributed. It is also important to point out that, according to an article in the November 2011 issue of the well-known and official publication *Revue française du Practicien* (a French magazine for the medical profession), only 1 to 10% of **serious** vaccine adverse effects are actually reported and logged (2). The extent of the problem is therefore grossly under-estimated.

The document also mentions no fewer than **37 other deaths of children recorded since the vaccine was launched in 2000, amounting to a minimum total of 73 infant deaths**.

We do not of course suggest that **all** these adverse effects are 100% and without doubt caused by this vaccine. It is however simply not credible to claim that *none* of these serious adverse effects or deaths were caused by the vaccine, given the fact that in most cases the victims were very young infants, newborns having only just taken their first breath and in perfectly good health prior to receiving the vaccine, and that in each case, there is also a relatively condemning time factor.

What is more, in 2006, a German study published in *Vaccine*, highlighted an unusually high number of infant deaths within the 48 hours following a hexavalent vaccine (3).

We notice that **the number of serious adverse events reported in this confidential document is totally different from the number specified in the GSK data sheet intended for doctors and pharmacists**, not to mention the information in the package insert intended for patients. This insert, incidentally, is not automatically handed to the parents by ONE workers who flippantly reassure parents that the only side effects of the vaccine are local such as a mild fever, slight pain or redness at the site of the injection, as specified on pseudo-informative labels which they stick hurriedly into the child's medical record (4)! As such, both doctors and patients are misinformed and do not receive the necessary guidance to even think of connecting the dots between various ailments and vaccination with Infanrix Hexa, a vaccine potentially administered only a few days or hours beforehand.

What would happen if this list of horrifying adverse effects were available to parents who might then discover in the list exactly the condition just diagnosed in their baby, very recently vaccinated, perhaps in order to be accepted at a nursery?

There is no question that some of them might feel compelled to initiate court cases, given that the manufacturer **and the authorities** were aware of these risks but simply ran rough-shod over the Belgian law of the 22nd August 2002 on patient rights, particularly its article 8 which specifies that to be able to make **a valid informed choice** and give their **consent**, patients (or legal guardians) MUST be provided with and have access to sufficient objective information including on the risks of the treatment offered.

Given all of the above, it is easy to understand GSK's desire for TOTAL confidentiality (the word 'confidential' is stamped on every single page) and we can also realize, sadly, that since the false swine flu 'pandemic' and the absolutely scandalous secret contract signed by Minister Onkelinx (5), the Belgian government's undercover attitude towards these matters has unfortunately not changed.

Another extremely salient aspect is that among the very serious adverse effects recorded by GSK we can see: **autism, sudden infant death (SIDS) and 'child abuse syndrome'** (6). These are all conditions which the health authorities have always denied to have even the slightest link with vaccines.

If however one reads carefully several of the reports of infant death included in this voluminous GSK tome, it appears that a number of them were reported to the company by national medicine authorities (in France, Italy, etc). It is therefore clear that these authorities and also doctors do acknowledge that it is possible, even probable, that such deaths are linked to this vaccine (7).

So how could the ONE have stated only a few months ago that "as far as nearly all of the medical profession worldwide is concerned, vaccines do not cause serious complications." (8)? Or how could they repeat that all adverse effects are monitored very carefully and that of course, if there were the slightest worrying signal, the situation would be re-investigated (9)??

It is also important to highlight that according to this document, **the number of sudden deaths in children over one year of age, occuring within three days of the Infanrix Hexa injection, exceeded the number expected** (10) while, remember: these data only represent between 1 and 10% of the serious adverse events which really took place! Worse still is that GSK is comparing this number of cases registered with a number of sudden deaths which can no longer be considered 'natural' or 'spontaneous' because today, nearly 100% of infants are vaccinated! If, in spite of this kind of

comparison which is already biased from the start, the number of cases reported exceeds the number expected, then it is really time to inform people! In addition, it is clear from this document that Infanrix Hexa is potentially even more dangerous than the other childhood vaccines.

Lastly, it is incredible to observe that GSK's criteria for seriousness are all relative: for example, GSK classifies events resulting in neurosurgery, reanimation or removal of part of the intestine as "minor" (11) while this kind of procedure would surely never be considered 'insignificant' in a very young child!

We at *Initiative Citoyenne* feel strongly that there is absolutely no justification for keeping all this incriminatory information away from the public, all the more so given that vaccines are paid for by the taxpayer.

Infanrix Hexa continues to raise far too many questions both in Belgium and throughout the world:

- Why, although the American authorities recommend all the individual vaccines in this hexavalent cocktail, is Infanrix Hexa used in Canada but not in the USA (12)?
- Why are Belgian parents forced, through the selective reimbursal system, to vaccinate their children with Infanrix Hexa in order to be accepted in a nursery when the Hepatitis B vaccine on its own is not mandatory and why is the pentavalent vaccine (without Hep B) available in France but not in Belgium (13)?
- Why have Ministers Onkelinx and Laanan never had the courtesy to reply to our last registered letter asking them why this pentavalent vaccine was not available in Belgium (14)?
- Could it be to favour GSK for whom Infanrix Hexa is a veritable cash cow due to the company's collection of patents as was openly explained last June by ex-CEO Jean Stéphenne in a video taken at the *Cercle du Lac* and also re-broadcast on RTBF last October (15)?
- Exactly how many Belgian children have died or continue to suffer from irreversible damage or incurable chronic diseases since this vaccine was introduced in 2004? How exact is the theoretical figure of only "one serious case for every million vaccinations", repeated ad infinitum by ONE in particular?
- Why has the clear listing of multiple sclerosis as a side effect, which appears on all the monovalent Hepatitis B vaccine AND also on the Infanrix Hexa package inserts, mysteriously disappeared from the latest versions of the reference books used by pharmacists?
- What would the results have been if in the pre-launch clinical trials of Infanrix Hexa the children vaccinated with this vaccine had been compared with another group of totally unvaccinated children who had never received a single vaccine in their lives? Would it not have been elementary and much more ethical to conduct this kind of trial BEFORE blindly subjecting all the children in the world to this kind of experimental vaccine?

As a citizens' watchdog, we demand that an urgent and in-depth enquiry be conducted into this vaccine, its effects and the real reasons behind its virtual imposition on all Belgian parents. It seems quite clear that once again, the reasons have less to do with 'the comfort of the infant' ('one less jab') and public health than with the business of the vaccine manufacturers and whatever other forms of intimidation and coercion are being used.

Initiative Citoyenne Watchdog

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