

Expert calls for calm as France hit by cancer vaccine scare

November 25 2013, by Angus Mackinnon

One of France's top medical experts appealed for calm Monday as a scare over a widely administered vaccine that prevents cervical cancer gathered momentum.

Daniel Floret, the chair of the national committee that oversees vaccinations, said there was no evidence to link Gardasil, a [vaccine](#) against the [human papilloma virus](#) (HPV), with serious auto-immune conditions such as multiple sclerosis.

Floret was responding to a criminal complaint filed by Marie-Oceane Bourguignon, 18, against Gardasil's French distributor, Sanofi Pasteur MSD.

The case was being given prominent play by France's media on Monday and Bourguignon herself gave a press conference in Bordeaux to describe how she believes taking the vaccine left her in a wheelchair, scarcely able to see or hear.

But Floret cautioned against reading too much into a single case.

"The fact that a complaint has been made does not mean there is a problem. We are putting all the focus on the potential side effects and forgetting what this vaccine brings," said Floret.

"None of the international medical safety controls has showed up any link between this vaccine and any kind of auto-immune disease, and

millions of doses have been administered."

Licensed for use in 120 countries, Gardasil has been given to 2.3 million French adolescents. It is one of two blockbuster HPV vaccines used around the world on the basis of research showing a link between HPV and cervical, oral and anal cancer.

In Britain, where the vaccine is offered to all girls between the ages of 12 and 13, the National Health Service estimates that the programme saves 400 lives per year.

'It has ruined our lives'

Bourguignon was vaccinated with Gardasil at the end of 2010 when she was 15. Within two months she had developed symptoms that included vertigo, vomiting, temporary loss of sight and the use of her legs, and facial paralysis.

"I was consumed by rage," her father, Jean-Jacques, 57, said on Monday. "For something like that to happen to a child in good health—it has ruined our lives."

According to her lawyer, Jean-Christophe Coubris, Bourguignon has been diagnosed as suffering from either an acute form of encephalomyelitis, a generalised inflammation of the immune system, or [multiple sclerosis](#).

Her legal case seeks to establish the liability of both Sanofi and France's medicines safety agency (ANSM), arguing that the latter body failed in its statutory duty of care when it authorised the vaccine.

According to Coubris, it is supported by the findings of a medical commission in the southwestern region of Aquitaine, which looked into

his client's case and concluded that she may have grounds for complaint, although a potential genetic vulnerability may also have been a factor. Sanofi contests the regional commission's findings and says they contradict the findings of numerous studies on the drug's possible side effects.

Three other women, aged between 20 and 25, will file similar complaints within the next fortnight, their Paris-based lawyer, Camille Kouchner, told AFP. The three women were all vaccinated between 2008 and 2010.

Two of them now suffer from a [chronic skin condition](#) known as Verneuil's disease or hidradenitis suppurativa, while the other one has polymyositis, a generalised inflammation of the muscles that gradually leads to paralysis.

Gardasil was devised by US pharma giant Merck & Co and approved for use by the Food and Drug Administration (FDA) in 2006. Its French distributor is a joint venture set up in 1994 between Merck's vaccine division and France's Sanofi Pasteur.

The other HPV vaccine is Cervarix, made by Britain's GlaxoSmithKline. It was licensed for use in the United States in 2009.

Nearly 530,000 women are diagnosed with [cervical cancer](#) annually worldwide and 275,000 die from the disease, according to the UN's World Health Organisation (WHO).

A third of teenage girls in America were vaccinated against HPV in 2010, a doubling compared with 2008, a study published in the US journal *Pediatrics* said in March.

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