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31st August 2010

FAO

Ms Nicola Sturgeon
Cabinet Secretary for Health and Wellbeing
St. Andrews House
Regent Road
Edinburgh
EH1 3DG

Dear Minister

My thirteen year old daughter was recently offered the HPV vaccine at school. Together with the consent form she was provided with a pamphlet, published on behalf of the Scottish Government by NHS Scotland, 'All you need to know about the HPV vaccine that reduces the risk of cervical cancer'.

Under the heading 'will there be any side effects?' the pamphlet stated that the side effects of the immunisation are "quite mild." I am writing to ask the Minister to consider this statement in light of Section 93 of the Medicines Act 1968. This clause makes it an offence for a party to circulate a misleading advertisement relating to a medicinal product:

93.(1) False or misleading advertisements and representations: Subject to the following provisions of this section, any person who, being a commercially interested party, or at the request or with the consent of a commercially interested party, issues, or causes another person to issue, a false or misleading advertisement relating to medicinal products of any description shall be guilty of an offence.

The Summary of Product Characteristics (SPC) included as part of the marketing authorisation for Cervarix, employs a three tier system for classifying adverse reactions to the vaccine: uncommon, common and very common and lists Myalgia (muscle pain) and athralgia (joint pain) as very common, while itching, rash, pruritis and urticaria along with nausea, vomiting, diarrhoea and abdominal pain as 'common'.

The SPC also lists Lymphadenopathy, anaphylactoid and anaphylactic reactions, angiodema, syncope or vasovagal responses to vaccination accompanied at

times with tonic-clonic movements the frequency of which cannot be quantified because they were reported in the post marketing surveillance 'spontaneously'.

As well as the acknowledged side effects in the manufacturers SPC, the Medicines and Health Care products Regulatory Agency (MHRA) have compiled an exhaustive list of adverse reactions reported to them following the administration of Cervarix vaccine, these range from the 'quite mild' to the more serious and debilitating, and in some instances, life threatening conditions.

The implications to a young person unfortunate enough to suffer adverse reactions, such as Lymphadenopathy, angiodema and anaphylactic adverse reactions, far exceeds the term 'quite mild' as listed in the NHS pamphlet. Whilst it may be accurate to describe *some* of the side effects as 'quite mild' it seems entirely misleading, particularly in view of the more serious side effects, to give the impression that *there are only* 'quite mild' side effects.

I consider that the information in the pamphlet on the HPV vaccine gives a misleading impression of the risks and the possible severity of some, influencing youngsters and their parents into believing that the ONLY possible adverse reactions they could suffer as a result of having this vaccine are the ones of the "quite mild" variety. How can it be said that informed consent has been obtained in these circumstances?

The principle that individuals, before undergoing a procedure, advocated by a health professional, are entitled to know the (identified) possible risks of that procedure has been tested and upheld in the case of Chester vs Afshar in the House of Lords. The individual's right to be advised of known risks associated with a procedure allowing for a full risk assessment was upheld along with the right to then decide in that knowledge, whether or not to proceed with the treatment advocated.

The Mail On Sunday article of the 29th August 2010 (" Anger over Cancer Jabs in Schools" by Jane Simpson) reports on how the law in Scotland upholds and recognises the rights of a minor under the age of sixteen years (deemed to have sufficient capacity) to consent to a procedure. Surely the law of Scotland also recognises the right of those same individuals to be provided with an accurate and more detailed account of possible risks associated with the procedure for which they are being asked to provide their consent.

The Executive spokesman quoted in the article recognises this right when he says "*The Law in Scotland is very clear- if a suitably qualified health professional judges a young person under sixteen is capable of understanding a procedure and **any possible consequences**, he or she can give or refuse consent independently*" (My emphasis added)

It follows that Scottish Law recognises the right of the child in respect of the Cevarix vaccine to be advised of "any possible consequences" which might befall them through agreeing to have this vaccine. I am concerned, that as things stand, the pamphlet being distributed to Scottish children does not comply with what the law intended in that it fails to advise of the range of possible side effects and the severity of some acknowledged reactions.

As a parent I would be grateful if you would give this matter your consideration particularly in view of Section 93 of the Medicines Act 1968 which was intended to prevent the distribution of misleading material in respect of a medicinal product. I am concerned that whilst healthcare providers, the manufacturers and agencies such as the MHRA are aware of the wide range of possible reactions to the Cervarix vaccine and the severity of some, our Scottish school children and their parents have to make do with a vague and non specific response of "side effects of the immunisation are quite mild". Given the content of both the SPC and the MHRA lists would the Minister not agree that this is at best unfair and at worst misleading?

Thank you

Yours sincerely

Wendy E Stephen

Cc Sir Robert Smith MP (by letter)
Mike Rumbles MSP (by letter)