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Briefing for the Public Petitions Committee

Petition Number: PE01658

Main Petitioner: Wendy Stephen

Subject: Compensation for those who suffered a neurological disability following administration of the Pluserix vaccine between 1988 and 1992

Calls on the Parliament to urge the Scottish Government to acknowledge and compensate individuals who suffered permanent neurological disabilities following administration of the Urabe mumps containing Pluserix MMR which was recommended and promoted by the Scottish Home and Health Department (SHHD) in their MMR vaccine campaign between October 1988 and September 1992.

Background

MMR vaccination and licensing

A combined measles, mumps and rubella vaccine (MMR-I) was first licensed in the UK in 1972. However, MMR-I was not actually used at that time because combined measles, mumps and rubella vaccines were not introduced into the UK routine childhood immunisation programme until 1988, by which time MMR-II had replaced MMR-I (differing in the rubella virus strain only). In the UK, one of the vaccines used contained a strain of the mumps virus called 'Urabe'. Others were available, from other manufacturers containing the 'Jeryl Lynn' strain of the mumps virus.

UK Bodies involved with decisions about vaccinations

The Report of the MMR Expert Group, published by the Scottish Government in 2002, describes in detail the roles and functions of the various bodies concerned with the safety of medicines, as well as providing detail on the strains of the diseases used in the vaccines. The document provides information about:

- the roles and responsibilities of the Joint Committee on Vaccination and Immunisation (JCVI), the Committee on Safety of Medicines

(CSM) and the Medicines Control Agency[1] (now MHRA) (paragraphs 4.1 to 4.6);

- How vaccines are tested, and the monitoring of adverse effects (paragraphs 4.7 to 4.18);
- the licensing of MMR vaccines (paragraphs 4.19 to 4.25)

The following table, taken from the above document shows the range of MMR vaccines licensed and used in the UK.

Components/strains of MMR used since 1988:

From 1988 to present:
MMR II*(Ender's Edmonston (measles), Wistar RA27/3 (rubella) and Jeryl Lynn (mumps) strains)*

From 1998 to present:
Priorix*(Schwarz (measles), Wistar RA27/3 (rubella) and RIT438 (derived from Jeryl Lynn (mumps) strains)*

From 1988/89 to September 1992 (no longer used due to presence of Urabe mumps strain):
Pluserix (licence now cancelled) **and Immravax***(Schwarz (measles), Wistar RA27/3 (rubella) and Urabe Am 9 (mumps) strains)*

The Pluserix vaccine was withdrawn from use by the manufacturer, not the UK government, in 1992.[2]

This press release from the Department of Health details the Medicines Control Agency's decision to cease the licence to import urabe containing vaccines in 2002.

urabe_050802.pdf

Issues raised about the urabe-containing mumps strain of the vaccine (Pluserix etc) leading to its withdrawal

The 2002 MMR Expert Group reported:

> **4.20** Five combined measles, mumps and rubella vaccines have been licensed in the UK (including MMR-I). Three of these are still licensed

[1] The Medicines Control Agency merged with the Medical Devices Agency in 2003 to become the Medicines and Healthcare Regulatory Products Agency (MHRA)
[2] Press report from 2007 providing background to the use and withdrawal of the particular vaccine

> and two (MMR II - Pasteur Merieux MSD and Priorix - GSK Biologicals) are routinely used in the national immunisation programme. Following the introduction of combined measles, mumps and rubella vaccine in 1988, sporadic case reports in the literature of mumps virus meningitis were reported in association with vaccines containing the Urabe Am 9 strain of mumps. Fewer cases were reported in association with combined measles, mumps and rubella vaccines containing the Jeryl Lynn strain. Since the Jeryl Lynn strain appeared to carry a lower risk of meningitis and meningo-encephalitis, only combined measles, mumps and rubella vaccines containing this strain were made available from 1992 (no licensing action has been taken against those containing Urabe Am 9 as the Committee on Safety of Medicines (CSM) concluded that the balance of risks and benefits remained positive).

This excerpt from Hansard from 1995 details a parliamentary question about the withdrawal of the urabe containing MMR vaccine in Canada (Trivirix), in 1990 and the subsequent research done in the UK, leading to its withdrawal from use and substitution with another vaccine:

> **Mr. Smith:** To ask the Secretary of State for Health what evaluation was made by his Department of the reasons why the Trivirix MMR vaccine was withdrawn from use in Canada in May 1990; what considerations led to his Department's to withdraw the MMR vaccine from use in the United Kingdom; and when it was withdrawn. *[40288]*
>
> **Mr. Sackville *[holding answer 31 October 1995]*:** The decisions that were taken by the Canadian authorities to discontinue using Urabe strain mumps vaccines were known to other licensing authorities. At that time, there was insufficient evidence of a problem with the strain of mumps vaccine in the United Kingdom for a change in vaccine policy to be advised.

Alerted to the existence of a potential problem of mumps vaccine virus meningitis, discovered in Canada, the Department of Health commissioned the public health laboratory service to undertake a study which allowed the detailed monitoring of possible vaccine associated cases. The studies undertaken were of an intensity that had not been undertaken anywhere else in the world. This involved 13 health districts. Some 28 vaccine associated cases were identified, all in recipients of MMR vaccines containing the Urabe mumps strain, indicating a risk of one in 11,000 with the vaccines.

As soon as data were available confirming the extent of the risk, showing that an alternative vaccine did not have this level of risk and was equally effective, and that adequate alternative supplies were available, the Urabe vaccines were replaced. This occurred in September 1992. The question remains as to why the UK continued with the vaccine for a further two years from 1990 – 92.

The Joint Committee on Vaccination and Immunisation (JCVI) and their consideration of the Urabe-containing vaccine

The JCVI is a UK standing advisory committee. The JCVI's terms of reference as agreed by the UK health departments are:

> "To advise UK health departments on immunisations for the prevention of infections and/or disease following due consideration of the evidence on the burden of disease, on vaccine safety and efficacy and on the impact and cost effectiveness of immunisation strategies. To consider and identify factors for the successful and effective implementation of immunisation strategies. To identify important knowledge gaps relating to immunisations or immunisation programmes where further research and/or surveillance should be considered."

There are many references in articles and grey literature to the JCVI's involvement and activity with this issue, which come from various minutes of meetings of the JCVI and its sub-committee, ARVI – Adverse Reactions to Vaccinations and Immunisations from 1989, which considered adverse reactions to the Urabe-containing vaccine. It is clear that the committee were familiar with the evidence from Canada at this time, where use of the vaccine discontinued 1990. In the JCVI minute, there is also reference to interest from the Procurator Fiscal, and the SHHD (Scottish Executive Home and Health Department) over the death of a child after vaccination.

Historic research

From a search of available academic literature published at the time, that is now available electronically, it appears that the Committee did not have access to the large body of evidence now available about the risks of this particular vaccine, on which to base its decisions and decided to proceed with using the urabe-containing strain.

This article from the American Journal of Epidemiology describes the action taken in the UK in response to the research done in Canada:

> At the time these MMR vaccines were introduced, Canadian investigators had reported that the Urabe mumps strain contained in two of the three available vaccines was temporally associated with aseptic meningitis in approximately 1 in 100,000 vaccinees (1). However, it was unclear at the time whether the association was causal and, if so, what the true attributable risk was and whether the adverse effect was exclusively related to vaccines containing the Urabe strain. Enhanced postlicensure surveillance was established in the United Kingdom using the British Paediatric Surveillance Unit scheme, whereby each month pediatricians are sent a card listing a set of defined conditions to be reported, to which meningoencephalitis after MMR vaccination was added… Subsequent epidemiologic studies using laboratory- and hospital-identified cases of aseptic meningitis linked to MMR vaccination records established that the true risk of MMR-associated aseptic meningitis was substantially higher than previously thought (~1 in 10,000–15,000 doses) and was exclusively related to the Urabe mumps strain in the vaccine.

Research continued and further studies were published after the withdrawal of the urabe-containing vaccine. Some of these are indicated in the article hyperlinked above.

UK Vaccine Damage Payment Scheme

The Vaccine Damage Payment Scheme was set up under The Vaccine Damage Payments Act 1979. Payment made under the Vaccine Damage Payment Scheme is not compensation and does not prejudice the right of the disabled person to pursue a claim for damages through the courts. Since its inception and up to 8 December 2014 6,026 claims have been received and 931 awards made, totalling about £73 million including top-up payments.[3]

If someone is severely disabled as a result of a vaccination against certain diseases, a one-off tax-free payment of £120,000 can be made. The payment might affect certain benefits and the eligibility criteria set out in the legislation include the following:

- You may receive payment if you're severely disabled and your disability was caused by vaccination against a number of diseases. The list includes mumps and MMR vaccines

- Disablement is worked out as a percentage, and 'severe disablement' means at least 60% disabled. This could be a mental or physical disablement and will be based on medical evidence from the doctors or hospitals involved in your treatment.

- You must normally have been vaccinated before your 18th birthday and in the UK or Isle of Man

- You can only claim for a child once they are 2 years old.

- To claim for an adult, apply by whichever is the latest of the following dates: on or before their 21st birthday (or if they've died, the date they would have reached 21), within 6 years of the vaccination

It is not known whether the petitioner made a claim under this scheme. If not, it would seem that the time limit has passed for her doing so now. However, as stated above, it is not a compensation scheme, and it is still possible to pursue a case through the courts, as the petitioner has done.

It appears that the petitioner is seeking compensation from the Scottish Government on the basis that at the time that her daughter and other children were vaccinated, between 1988 and 1992 (ie prior to devolution) the then Scottish Home and Health Department was aware of the risks associated with this particular vaccine.

[3] From FOI response recorded by www.whatdotheyknow.com; https://www.whatdotheyknow.com/request/number_of_people_who_received_co

Taking further court action

Usually, when someone has suffered personal injury as a result of a defective product, they can sue the producers of the product for compensation. This is what the petitioner had attempted to do in her previous legal action.

However, the law places limits on the length of time someone has to raise court action in these circumstances. The law in this area is complicated, and there are different time periods in relation to different types of claim.

Personal injury actions usually have to be raised within three years of the injury occurring. Where all the relevant factors – eg. who is responsible for the injury – are not known, the time limit starts running from the date that they reasonably should have been known. This legal doctrine is known as "limitation".

The court can extend the three year limitation deadline where it is "equitable" to do so. This will involve consideration of the interests of both sides to the court action. In practice, the deadline is rarely changed.

Periods of time when someone is under the age of 18 are not counted for the purpose of calculating the limitation period. This is relevant, as the constituent's daughter was very young when the injury happened. The limitation period would not have started running until she was 18.

Separately, the right to take court action can be extinguished entirely after a certain amount of time has passed. This legal doctrine is known as "prescription". The court has no discretion to extend the time periods relevant for prescription. When the deadline has passed, the right to take action is lost irretrievably.

The right to sue for defective products under consumer protection legislation prescribes after 10 years. The petitioner's original court claim seems to have been based on liability under this legislation.

However, it may still be possible to bring an action based on the general law of negligence after this time period. The right to bring court action for personal injury due to negligence never prescribes.

Voluntary payments

It is open to any of the organisations involved to make a voluntary payment to the constituent's daughter in compensation for her injuries. This would include the Scottish Government, acting as the body which has taken on the obligations of the Scottish Home and Health Department.

Such voluntary payments are often known as an "ex gratia" payment. They are made as a gesture of goodwill, even though there may be no legal obligation to do so.

Scottish Government Action

The Scottish Government/NHS Scotland has a website dedicated to immunisation: Immunisation Scotland providing public information about all the different vaccines currently offered.

Scottish Vaccine Update, published regularly by NHS Health Protection Scotland providing healthcare professionals with information and practical advice.

Statutory relationship to the UK Joint Committee on Vaccination and Immunisation (JCVI)

The JCVI has no statutory basis for providing advice to Ministers in Scotland or Northern Ireland (see JCVI statement above) However, health departments from these countries may choose to accept the Committee's advice or recommendations. Specific advice given by JCVI in response to a request from any one UK health department or Minister is not binding on any of the other Ministers of the Devolved Administrations or UK Government. UK health departments are made aware of all JCVI advice through their designated observers who attend JCVI and Sub-committee meetings and receive committee papers.

Further information and studies

From Cochrane Review 2012

> Results from two very large case series studies involving about 1,500,000 children who were given the MMR vaccine containing Urabe or Leningrad-Zagreb strains show this vaccine to be associated with aseptic meningitis;

Institute of Medicine. 1994. *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. Washington, DC: The National Academies Press. doi: 10.17226/2138.

The UK Department of Health issues the 'Green Book' which has information on vaccines and vaccination procedures, for vaccine preventable infectious diseases in the UK. The following is taken from the 2013 Green Book:

One strain of mumps virus (Urabe) in an MMR vaccine previously used in the UK was associated with an increased risk of aseptic meningitis (Miller et al., 1993). This vaccine was replaced in 1992 (Department of Health,1992) and is no longer licensed in the UK. A study in Finland using MMR containing a different mumps strain (Jeryl Lynn), similar to those strains used currently in MMR in the UK, did not identify any association between MMR and aseptic meningitis (Makela et al., 2002).

Medical journal articles published on links between MMR and mumps meningitis from 1988 - 1993

newspaper report that refers to the Katie Stephen case - Telegraph 2007 – '*Early fears about MMR in secret papers'*

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