

Document 1

From: [redacted] **On Behalf Of** DG Health & Social Care
Sent: 03 July 2017 11:15
To: [redacted]
Subject: RE: PE1658 - Pluserix vaccine - by Friday 28 July

Hi

The Public Petitions Committee considered the above petition for the first time at its meeting on 22 June 2017, at which it took evidence from the petitioner.



20170703ACtoS...

The Committee agreed to seek the Scottish Government's views on the action called for in the petition. The Committee asks—

- whether the Scottish Government has been aware of, and looked at this issue
- whether the Scottish Government would consider voluntary ex gratia payments
- how any such payments would be calculated.

Deadline for **response is by Friday 28 July.**

Regards

[redacted]

[redacted] |Private Secretary to Paul Gray |DG Health and Social Care and Chief Executive
NHS Scotland|Rm 1E.16 |SAH
☎ [redacted]

From: [redacted] **On Behalf Of** DG Health & Social Care
Sent: 21 June 2017 11:15
To: [redacted]
Cc: [redacted] DG Health & Social Care
Subject: FW: Public Petitions Committee Meeting - 22 June 2017 - PE1658 - Pluserix vaccine

Hi

At its meeting tomorrow the Committee will consider a new petition and take evidence from the petitioner:

PE1658 by [redacted] on Compensation for those who suffered a neurological disability following administration of the Pluserix vaccine between 1988 and 1992.

I see there is previous correspondence:

<http://s0842a/MACCS/CaseDetailView.aspx?c=20160035758>

Please see the papers below. The Committee may write to seek SG views.

Regards

[redacted]

[redacted] |Private Secretary to Paul Gray |DG Health and Social Care and Chief Executive
NHS Scotland|Rm 1E.16 |SAH

📧 [redacted]

From: [redacted]

Sent: 21 June 2017 10:35

To: [redacted]

Cc: DG Communities; DG Economy; DG Finance Mailbox; DG Health & Social Care; DG Learning & Justice; DG Strategy and Operations; [redacted]; PS/Transport Scotland

Subject: Public Petitions Committee Meeting - 22 June 2017

PUBLIC PETITIONS COMMITTEE MEETING

1. The Public Petitions Committee will meet on 22 June 2017. A copy of the agenda and papers is given below.
2. The agenda will cover 2 current petitions and 3 new petitions.
3. Could you please consider any petitions falling within your direct area of responsibility and cascade to Directorates with a direct policy interest for information.

[redacted]

Parliament and Governance Team
40369

<< File: Agenda and Papers - 22 June 2017.pdf >>

Email attachment:



The Scottish Parliament
Pàrlamaid na h-Alba

PUBLIC PETITIONS COMMITTEE

By email:

[redacted]

Committee Liaison Officer

Scottish Government

[redacted]

Cc: dghsc@gov.scot

[redacted]

All correspondence c/o:

Public Petitions Clerks
Room T3.40
The Scottish Parliament
Edinburgh
EH99 1SP
Tel: 0131 348 5982
Type Talk Direct No. 18001 0131 348 5982
petitions@parliament.scot

3 July 2017

Dear [redacted],

CONSIDERATION OF PETITION PE1658 (Compensation for those who suffered a neurological disability following administration of the Pluserix vaccine between 1988 and 1992)

Calling on the Scottish 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.

The Public Petitions Committee considered the above petition for the first time at its meeting on 22 June 2017, at which it took evidence from the petitioner.

The Committee agreed to seek the Scottish Government's views on the action called for in the petition. The Committee asks—

- whether the Scottish Government has been aware of, and looked at this issue
- whether the Scottish Government would consider voluntary ex gratia payments
- how any such payments would be calculated.

I would be **grateful to receive your response by Friday 28 July**. Your response will be processed in line with the Parliament's policy on the treatment of written evidence. It would be helpful to receive your response in Word format.

The Committee asks that this deadline is met to allow sufficient time for the petitioner to comment on your response and for consideration of the petition to continue as timetabled. If you are unable to meet the deadline set out above, please contact me as soon as possible.

The Official Report of the meeting is available at:

<http://www.parliament.scot/parliamentarybusiness/report.aspx?r=11036&i=100801#ScotParlOR>

You can view the Committee's consideration of the petition at:

http://www.scottishparliament.tv/20170622_public_pets?in=01:36:08&out=02:01:28

Yours sincerely,

[redacted]

Assistant Clerk

Public Petitions Committee

Document 2

From: [redacted]

Sent: 12 July 2017 17:08

To: [redacted]

Cc: [redacted]

Hi [redacted]

Yes, the Agency was contacted by the Committee clerk. However, on reading the transcript, and as it focuses entirely on matters of compensation and the policy of using Pluserix at the time, we intend to state that the issues are outside of the Agency's remit and have no comments to make, and will refer them to DH and DWP for more info on immunisation policy and VDPS. We will acknowledge that the former MCA and CSM undertook an assessment of the evidence of risk of aseptic meningitis with Pluserix (and other Urabe mumps vaccines) in 1992 and 2002, but that such assessments were unrelated to compensation matters.

As a general contribution on MHRA (and distinguishing our role from imms policy) role for your response, how does this sound?

"The Medicines and Healthcare products Regulatory Agency (MHRA) [formerly the Medicines Control Agency] has statutory responsibility for the safety of medicines and vaccines in the UK. The MHRA takes advice from the Government's independent expert advisory body, the Commission on Human Medicines (CHM) [formerly the Committee on Safety of Medicines], when evaluating the risks and benefits of medicines and vaccines. Matters of immunisation policy are independent from MHRA and medicines regulation".

Happy to discuss.

Best wishes

[redacted]

[redacted] | **Vaccines, Anti-infectives and Advanced Therapies Unit | Vigilance and Risk Management of Medicines (VRMM) | MHRA | 4th floor, 151 Buckingham Palace Road, London, SW1W 9SZ | T: [redacted]**

MHRA is a centre of the Medicines and Healthcare Products Regulatory Agency

Stay connected: mhra.gov.uk/stayconnected

Please note MHRA email addresses have changed. From Monday 10 April, all @MHRA email addresses have dropped the .gsi – see signature above. Please update your contacts accordingly. Emails sent to the old addresses will continue to be forwarded until further notice.

From: [redacted]

Sent: 11 July 2017 17:08

To: [redacted]
Cc: [redacted]
Subject: Petition PE1658 - Pluserix Vaccine

Good afternoon [redacted],

cc as above

Please see the link to the official record for a new Petition which was heard on Thursday 22 June 2017

<http://www.parliament.scot/parliamentarybusiness/report.aspx?r=11036&i=100801#ScotParl>
OR

As you may be aware, the petitioner is calling for the Scottish 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 (then) Scottish Home and Health Department in their MMR vaccine campaign between Oct 1988 and September 1992.

I believe that the Public Petitions Committee have said that they will write to the MHRA directly to seek views on the issues raised in the petition. Grateful if you could confirm that they have done so and that you are intending to respond.

While we consider our response it would be helpful to have a contribution from you on the role of the MHRA and its responsibilities for vaccine safety across the UK so that we can include an accurate insight into this element of the wider vaccination programme structures. That would be welcome.

The petitioner seems to indicate that there was a vaccine damage payment unit that acknowledged there was a problem with the vaccine. Perhaps you are in a position to elaborate further on that particular aspect please?

Anything else you think that would be relevant for us to highlight in our response would be much appreciated.

Grateful to have a response from you by cop of play 18 July 2017 if possible please to allow us time to pull together a full response for the PPC.

Happy to discuss,

[redacted]

11 / 7

Kind regards

[redacted]

National Programmes - Vaccination / Immunisation / Screening

Health Protection Division | Population Health Directorate | Scottish Government | 3 East St
Andrews House, Regent Road, Edinburgh EH1 3DG | [redacted]

Document 3

From: [redacted]

Sent: 11 July 2017 17:08

To: 'petitions@parliament.scot'

Cc: DG Health & Social Care <DGHSC@gov.scot>; Brown GJ (Gareth) <Gareth.Brown@gov.scot>

Subject: Petition PE1658 - Pluserix Vaccine

Dear [redacted]



Response to
Petition PE1658....

Please find attached the Scottish Government's response to petition PE1658.

Many thanks

[redacted]

28/7

Kind regards

[redacted]

National Programmes - Vaccination / Immunisation

Health Protection Division | Population Health Directorate | Scottish Government | 3 East St
Andrews House, Regent Road, Edinburgh EH1 3DG | [redacted]

Attachment:

Population Health Directorate
Health Protection Division



Scottish Government
Riaghaltas na h-Alba
gov.scot

T: 0131-244 6910

E: gareth.brown@gov.scot

Mr [redacted]

Assistant Clerk

Public Petitions Committee

The Scottish Parliament

EDINBURGH

EH99 1SP

28 July 2017

Dear Mr [redacted]

CONSIDERATION OF PETITION PE1658

Thank you for your letter of 3 July 2017 seeking the Scottish Government's views on the action called for in Petition PE1658 namely;

- whether the Scottish Government has been aware of, and looked at this issue
- whether the Scottish Government would consider voluntary ex gratia payments
- how any such payments would be calculated.

The Scottish Government is aware of this historical issue, which relates to the Urabe-containing MMR vaccine which the Scottish Home and Health Department (SHHD) promoted in its MMR vaccine campaign between October 1988 and September 1992. You will appreciate that these events pre-date devolution and relate to decisions made at the time by the UK Government.

Vaccination policy, at the time, was based on the expert advice of the Joint Committee on Vaccination and Immunisation (JCVI). I understand that in making its recommendations on MMR vaccine at the time, the JCVI did consider reported adverse reactions to the Urabe-containing vaccine. However 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. Once data were available confirming the extent of the risk and that an alternative vaccine was available, the Urabe strain mump vaccines were replaced. It is of course regrettable that anyone was affected as a result of efforts to protect the population against disease, and I fully sympathise with those individuals and their families.

The safety of medicines, and policy on compensation for vaccines damages, are issues which are reserved to the UK Parliament. Disability or damage caused by a vaccination against mumps is covered by the Vaccine Damages Payments Scheme, which is administered by the Department for Work and Pensions. I am aware that there is a disability threshold for payments under the VDPS, and I know that the Committee has heard evidence that some of those who were affected by the Urabe-containing vaccine have not been judged to have met this threshold and consequently, they have not received any payment. The policy for payments under the scheme, including thresholds at which payments are made, is a matter for the Department of Work and Pensions, and it would be useful for the Committee to seek a view from the DWP on this issue.

Given that these are matters reserved to the UK Parliament, I can confirm that the Scottish Government has no plans to set up a scheme as suggested by the petition.

I hope that this response is helpful.



GARETH BROWN

Head of Health Protection Division



The Scottish Parliament
Pàrlamaid na h-Alba

Mike Rumbles MSP
Member of the Scottish Parliament for North East Scotland

Aileen Campbell MSP
Minister for Public Health and Sport
St. Andrews House
Regent Road
Edinburgh
EH1 3DG

Dear Aileen,

Tuesday 12th September 2017

Please find the enclosed letter to Johann Lamont (Convener of the Public Petitions Committee).

I would welcome your views on this matter.

Mike

Mike Rumbles MSP





The Scottish Parliament
Pàrlamaid na h-Alba

Mike Rumbles MSP

Member of the Scottish Parliament for North East Scotland

Public Petitions Committee
FAO: Johann Lamont MSP (Convener)
The Scottish Parliament
Edinburgh
EH99 1SP

Tuesday 12th September 2017

I am writing to you on behalf of my constituent, , who has raised with me her concerns about the definition and practice of informed consent for vaccination and medical treatment in Scotland.

She first raised this issue with me in 2010 and I know that she recently presented evidence to the Public Petitions Committee regarding this matter.

I am deeply troubled that there appears to be significant equivocation on this issue, both with the practice of informed consent and in regards to reparations for patients who have been harmed through medical treatment.

As I understand it, the Scottish Government is ultimately responsible for setting out clear guidelines based on the evidence available. It is also responsible for clearly defining the meaning of both of the terms 'informed consent' and 'compensation'. Given the information provided by Ms Stephen, which I have enclosed for you, it appears that this matter has been further complicated by a misrepresentation of those terms in the correspondence between the Scottish Government and the Public Petitions Committee and in the Health System as a whole.

At the very least, it seems to me, there is a lack of will to get to grips with this issue and make the necessary changes needed to ensure that all patients undergoing any medical treatment have a satisfactory level of information available and that suitable reparations are available to those whose lives may be altered due to a failed procedure or vaccination.

I would be very grateful if you could look into this matter and respond to my concerns.

For your information, I have also written to Aileen Campbell, Minister for Public Health and Sport, enclosing a copy of this letter.

I look forward to reading your reply.

Mike Rumbles MSP

cc. Aileen Campbell MSP (Minister for Public Health and Sport)

Extracts for the email of I

to Mike Rumbles MSP (07/09/17):

I appear[ed] before the Petitions Committee to give evidence in support of my petition (PE 1658). In conclusion, the committee decided to write to the Government and raise the issues in my petition. On 28th July 2017 the Committee received a response from the Scottish Government which was posted on the petitions website (PE 1658 B)

I have submitted a response which I attach for your interest. My response is self-explanatory but I am now writing to ask for your support in this matter. The Executive's response was nothing short of incredulous with them seeking to avoid their responsibilities by promoting an idea that the Vaccine Damage Payment Unit (or the VDPS scheme) is the place for the Pluserix victims to go to obtain compensation when they knew, at all times, that their own SPICe briefing attached to my petition, recorded the fact that it was not a scheme to award compensation.

I feel that there [may have been] an intention to mislead the Petitions Committee in suggesting to them that this was an option available to the Pluserix vaccine victims. I feel it is unfair that I am having to shoulder a burden to [inform] the petitions committee not only in correcting factual information but also to the fact that the information was circulated at the outset in the SPICe briefing.

Additionally, despite the Scottish Government acknowledging wrongdoing to other Scottish subjects by parties prior to devolution and which came about as a result of legislation from the UK Government, they steadfastly refuse to acknowledge the Pluserix victims and I have to wonder what that is about.

They do not deny their existence but refuse to either recognise them and compensate them.

I would be very grateful of your support in this matter. Their disgusting attempt to offset the damaged victims against their intention to protect the nation against preventable childhood diseases through vaccination by offering up regrets and sympathy, is quite frankly, the worst thing I have heard in over 20 years of campaigning on this subject.

PE1658/C

Petitioner submission of 15 August 2017

The purpose of my petition was two fold, to secure an acknowledgement of the damage sustained by Scottish children following administration of the Urabe containing Pluserix vaccine, and compensation to the victims for their lasting disabilities.

"Calling on the Scottish 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"

The submission from the Scottish Government states that "policy on compensation for vaccine damages" is a matter reserved to the UK Parliament via the Vaccine Damage Payment Scheme (VDPS).

The Scottish Government is aware that the VDPS is not, and never has been, a compensatory scheme with every reference to the scheme rigorously stating that an award is not compensation. This information was circulated in the Scottish Parliament Information Centre (SPICe) briefing on 12th May 2017 and appears alongside my petition on the website:

"Payment made under the Vaccine Damage Payment Scheme is not compensation..."

It has never been an option for the Pluserix vaccine damaged individuals to get compensation for their injuries from the VDPS which provides a one off payment to "ease the present and future burdens of the vaccine-damaged person and their family". That is entirely different to a compensatory award which is being sought in this petition.

Compensation is defined in the dictionary as "something, typically money, awarded to someone in recognition of loss, suffering, or injury".

It is not in dispute that the Pluserix victims endured a negative impact with the Scottish Government acknowledging in their response that individuals were "affected" by the vaccine:

"It is of course regrettable that anyone was affected as a result of efforts to protect the population against disease, and I fully sympathise with those individuals and their families"

Whilst choosing not to initiate a system of exgratia payments for the Pluserix vaccine victims, the Scottish Government has sought to circumvent their liability by suggesting that the VDPS scheme provides compensatory awards to vaccine damaged applicants. Additionally, they argue that the "events" pre-dated devolution and "relate to decisions made at the time by the UK Government" neither of which

"It is of course regrettable that anyone was affected as a result of efforts to protect the population against disease, and I fully sympathise with those individuals and their families".



T: 0300 244 4000
E: scottish.ministers@gov.scot

Mr Mike Rumbles MSP
The Scottish Parliament
EDINBURGH
EH99 1SP

Our ref: 2017/0034274
October 2017

Thank you for your letter of 12 September seeking my views on the matters raised in your correspondence to Johann Lamont, Convener of the Public Petitions Committee. In particular you raise two issues; informed consent and reparation for individuals who believe they have been harmed by medical treatment, which I'd like to address in turn.

With regards informed consent for vaccinations in Scotland, this is a matter the Scottish Government takes very seriously. Informed consent is a central part of all vaccination programmes in Scotland. Whilst I cannot comment on the informed consent process for vaccinations given during the 1980s and early 1990s I can set out the process for informed consent as it is now for routine childhood vaccinations.

Prior to any babies receiving their vaccinations, there are multiple touch points at which parents are provided with information about the different vaccinations offered throughout childhood. During pregnancy, parents are given a copy of the '*Ready, Steady, Baby!*' book, and at the child's birth they receive a Personal Child Health Record (also known as the Red Book). On day 10 or so, after the child's birth, the community nurse takes over from the midwife and as part of their engagement with parents provides and discusses the guide to childhood vaccinations up to 5 years of age. Each of these communication materials given to parents before and after the birth of their child contains information on the vaccines available for babies as well as signposting them to the immunisation Scotland website where they can find out more information. Once a child reaches the appropriate age for their first vaccination (usually around 2 months/8 weeks of age) they will be invited to attend their GP Practice for vaccination. Having been provided with all the information about the vaccinations offered, parents can then decide whether they wish to attend the appointment to have their child vaccinated.

Turning now to the point about reparation, the Scottish Government of course recognises that the Vaccine Damage Payment Scheme (VDPS) does not award compensation. The

VDPS, does however, remain the correct route for individuals to go through if they believe they have been severely disabled as a result of a vaccination against certain diseases. Although I recognise this is not what your constituent will want, the Scottish Government has no plans to establish a scheme as suggested by your constituent.

Aileen Campbell