

From: [REDACTED]  
Sent: 17 May 2018 10:36:17  
To: Public Engagement Unit  
Cc: Cabinet Secretary for Health and Sport, [REDACTED]  
Subject: FW: Medical Devices U.K.

PEU

Please could this be scanned on to MACCS as an MR.

Please could you ensure it is scanned on today. Please could you assign the case to [REDACTED]

Copying [REDACTED] in for his awareness. [REDACTED] - this is the issue we were discussing earlier.

Regards

[REDACTED]  
Deputy Private Secretary  
Ministerial Private Office (Health)  
St Andrew's House  
[REDACTED]

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From: [REDACTED] On Behalf Of Deputy First Minister and Cabinet Secretary for Education and Skills  
Sent: 17 May 2018 10:25  
To: Cabinet Secretary for Health and Sport  
Cc: Deputy First Minister and Cabinet Secretary for Education and Skills  
Subject: FW: Medical Devices U.K.

Hi [REDACTED]

DFM asked that I pass on the below correspondence to Ms Robison.

Thanks  
[REDACTED]

[REDACTED] | Deputy Private Secretary to John Swinney MSP | Deputy First Minister of Scotland and Cabinet Secretary for Education & Skills | Scottish Government | St Andrew's House | Edinburgh | EH1 3DG | T: [REDACTED] E: [DFMCSE@gov.scot](mailto:DFMCSE@gov.scot)<<mailto:DFMCSE@gov.scot>>

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From: Swinney J (John), MSP [mailto:John.Swinney.msp@parliament.scot]  
Sent: 17 May 2018 10:04  
To: Deputy First Minister and Cabinet Secretary for Education and Skills  
Subject: Medical Devices U.K.

Could you please pass this to Ms Robisons's Ministerial Office.

Thanks.

J

Dear Shona,

Medical Devices UK

I refer to our conversation on Tuesday regarding the concerns of Medical Devices U.K., a company based in my Constituency, regarding their contractual arrangements with NHS Grampian.

Medical Devices U.K. provides an independent testing and validation service for decontamination facilities of a medical device. The scheduled testing programme is to assess that the equipment is operating to the defined parameters of the commissioning data recorded at the time of the installation process. The company provides these services at Aberdeen Royal Infirmary and at other NHS sites through a framework contract that has brought savings to the NHS.

In both September 2017 and February 2018 the company identified potential patient safety risks due to changes to the processes for cleaning equipment to ensure effective decontamination. I understand that the event in September 2017 was rectified but the event in February 2018 May not have been.

This issue has been raised by the company through Alex Neil MSP with whom you corresponded on 21 March and 24 April. The company point out that in your letter of 21 March, you state :

"Finally, with reference to there being four safety breaches in Aberdeen Royal Infirmary Endoscopy Department, the Health Board advises that no such incidents have been reported."

In your letter of 24 April, the company point out that you state :

"The Health Board also confirms that any potentially adverse events relating to the decontamination services have been fully reported, investigated and concluded satisfactorily."

The company make the point that there appears to be a contradiction between these two statements. In addition, they make the point that they do not believe the statement quoted from your letter of 24 April to be accurate as they believe not all of the incidents have been rectified.

The company have raised these concerns - as they are contractually bound to do - and

now find that they are no longer to be used by Aberdeen Royal Infirmary to provide these validation services.

I would be grateful if these concerns could be looked into with vigour to provide clarity for my constituents.

I look forward to hearing from you.

Yours sincerely,

John

John Swinney  
MSP for Perthshire North

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

Mr John Swinney MSP  
The Scottish Parliament  
EDINBURGH  
EH99 1SP

Our ref: 2018/0016281  
13 June 2018

Dear John,

Thank you for your email of 17 May concerning Medical Devices UK and decontamination services within NHS Grampian.

As you are aware, I have previously corresponded with Alex Neil on this issue and, in light of the concerns raised by Mr Neil, the Health Board confirmed that it is making arrangements for the in-house provision of decontamination services and is doing so in full compliance with the requirements of the NHS Scotland framework contract, as confirmed with the relevant Commodity Manager at NHS National Procurement.

With respect to the suggested inconsistency concerning potential safety breaches or adverse events, the Health Board confirms that it reports and reviews all adverse events and, where required, also conducts a formal investigation. The Health Board is aware of [REDACTED] concerns, but has been clear throughout that all potential patient-safety concerns have been reviewed and addressed satisfactorily. These reviews have not indicated any actual patient safety impact of a type that the Health Board understands was suggested by [REDACTED]

The adverse events that [REDACTED] has referred to were reported to Incident Reporting and Investigation Centre (as per standard procedure) and, as appropriate, these were investigated by a multi-disciplinary team that included input from Health Facilities Scotland. The outcomes of the investigations showed that it was very unlikely that actual patient safety had been compromised. With respect to issues that [REDACTED] believes have not been rectified, the Health Board is unclear as to what is being referred to.

On 15 May the Health Board had a decontamination expert team from Health Facilities Scotland review the management of the issues raised by [REDACTED] and also our current service arrangements. This was primarily in response [REDACTED] continuing challenges. Whilst the Health Board awaits the written report from Health Facilities Scotland, verbal feedback was that that they support the previous investigation outcomes which

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indicates that the chance of any actual patient harm associated with the issues raised by [REDACTED] [REDACTED] was very low indeed.

I am aware that the Health Board offered to meet [REDACTED] on 14 May in order to attempt to move forward from the present situation, though I understand that [REDACTED] subsequently declined the offer. The Health Board confirms that it plans to repeat the offer of a structured meeting to try to better understand [REDACTED] position, and explore how a viable supplier relationship might be re-established and sustained, and I would hope that [REDACTED] [REDACTED] feels in a position to accept the offer.



SHONA ROBISON

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