PS MINUTE FOR CASE 2018/0024778

This is the latest in a short series of letters received on behalf of Medical Devices UK.

NHS Grampian have taken a decision to move to in-house decontamination services, with Medical Devices UK gaining less business from the Health Board as a result.

The Health Board met with [REDACTED – PERSONAL INFORMATION (S38(1)(B)] in June because it considers its relationship with Medical Devices UK to have become increasingly unsatisfactory, partly linked to NHS Grampian's reduced spend with that supplier and also its attempts to address a number of contract performance issues. [REDACTED – PERSONAL INFORMATION (S38(1)(B)] has made many and varied allegations though several routes to NHS Grampian, all of which the Health Board believes have been addressed thoroughly and satisfactorily.

Previous correspondence is attached here.

Correspondence with Alex Neil, February 2018

From: Neil A (Alex), MSP [mailto:Alex.Neil.msp@parliament.scot]
Sent: 21 February 2018 10:13
To: Cabinet Secretary for Health and Sport
Subject: NHSS National Framework Contract for Decontamination Devices-Grampian NHS
Importance: High

Dear Shona

I have been asked by one of my constituents, who wishes to remain anonymous, to bring the following situation to your attention, as it presents a potential risk to patient safety in NHS Grampian

Despite there being an NHSS National Framework Contract for Decontamination Devices it appears that the Head of Decontamination within NHS Grampian has stopped using these approved contractors for certain devices.

For example a company which isn't a Framework contractor has been brought in provide endoscope storage cabinets and apparently safety requirements are being flouted.

For example: the new company apparently does not possess an appropriate certification; safety features are being overridden; there is a question mark over whether it has the necessary indemnity insurance for the work it is doing; as well as a question mark over whether the service components are being changed every 6 months as they are required to be to protect patient safety/desiccant filter issues.

I am informed that there have been 4 safety breaches in Aberdeen Royal Infirmary Endoscopy Department since this company took over the contract, including a failed BSI audit.

Clearly if these allegations are true then urgent action is needed to investigate why a non-Framework contractor is being used and what action now needs to be taken to ensure that patient safety is not being compromised.

Meantime I would appreciate it if you could please advise your response

In appreciation

Yours sincerely

Alex Neil MSP

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*

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Cabinet Secretary for Health and Sport
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Mr Alex Neil MSP
The Scottish Parliament
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Our ref: 2018/0006670
March 2018

Thank you for your email of 21 February concerning decontamination services at NHS Grampian.

The Health Board has confirmed that its decontamination service abides by the arrangements put in place by NHS National Procurement with regard to the NHS Scotland National Framework Contract for Decontamination Services. I understand that, at present, the Health Board does not have a service contract in place for the testing and validation of endoscopy service cabinets with a framework contractor. Instead, arrangements are being put in place to transition the work from a previous contract to in-house provision, with the aim of achieving best value for the organisation whilst maintaining the highest possible level of patient care.

Whilst the transition is underway, the service has engaged appropriate short-term training and support from a third party company who have the necessary qualifications and expertise to provide this. The Health Board confirms that this has been done 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 BSI Audit, NHS Grampian confirms that its decontamination service holds certification to BS EN ISO 13485 for all areas, and has never failed an audit. The most recent audit took place in February, with the outcome being a recommendation for the continuation of certification.

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.

I hope this is helpful.

SHONA ROBISON

Correspondence with Alex Neil, March 2018

Dear Shona
Many thanks for your reply to me dated 21st March regarding decontamination services in NHS Grampian
I have shared your response with my constituent, who wishes to remain anonymous
Please find attached his comments
I would appreciate you giving detailed consideration to each of the points and advice accordingly
Meantime I look forward to hearing from you
Yours sincerely
Alex Neil MSP
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Hi Alex,
Thank you for forwarding over the response from Shona Robinson.
I would like to make some comments in response to the letter received.
Paragraph 1
Arrangements are being put in place to transition the work from a previous contract to in-house provision, with the aim of achieving best value for the organisation whilst maintaining the highest possible level of patient care.
All trusts agreed to sign up to a national contract to achieve best value from suppliers awarded national contracts,
All suppliers where asked to fix pricing throughout the framework period to enable the trust to budget.
This framework has now been extended for 25 months to allow national procurement to evaluate cost savings and publish a new framework agreement; suppliers again being ask to fix prices this would be a price fix for 5 years in total.
When the hospital wants to transition to in-house for best value this can only be achieved when the persons carrying out the work have the correct skill set qualifications and are changing out the stipulated components at each service interval. Otherwise the risk to patient safety is being compromised by cost for which budgets had been set aside, the criteria tendered for on the national

contract from the OJEU is not being carried out in accordance with the minimum requirements and to the standard BS EN 16442:2015 Controlled environment storage cabinet for processed thermolabile endoscopes.

Paragraph 2

Whilst the transition is underway, the service has engaged appropriate short - term training and support from a third party company who have the necessary qualifications and expertise to provide this. The health board confirm that this has been done in full compliance with the requirements of NHS Scotland framework contract, as confirmed with the relevant commodity manager at NHS procurement.

How long will the transition period be as the machines are still in use without a proper validation being performed?

The third party company who is providing the training to in-house staff has no manufacturer equipment experience, not approved by NHS framework or the OJEU for maintenance & testing of any Medical Device, it has never had to produce public liabilities insurance to the sum of £10,000,000 or never met the minimum requirements of the OJEU for quality management system ISO 9001: 2015 this is costs that all small companies have to endure to set up these systems to meet the basic requirement to apply for the national contracts.

Have we ignored the minimum requirements and risked patient safety?

What is the best value of using a non-approved contractor who has none of the above?

While we accept it is NHS Grampians decision to whom they allow to work on there equipment I must call to action the rational behind this decision on allowing an unqualified company to train unqualified personnel with no electrical, mechanical or electronic background to service and test medical equipment for use in patients.

NHS has a policy of any person working on equipment must be employed by estates department with a minimum 5 years electrical, mechanical trade experience before you can apply for a job as a band 5 test person.

The individuals being trained to carryout this work, have no such skill set and the jobs have never been advertised to persons with the relevant qualifications

Is this a question for HSE or Trade unions?

What is the value of the work being contracted out to the third party company should this have gone out to public tender?

This is an off contract spend surely this had to be carried out under a mini tender process at least.

Can the company providing the training assist with the health board providing a sample test report for the validation work undertaken that meets the requirements of the OJEU National procurements tender qualification envelope.

This should include but not limited to Manufacturers Certification of competency, Certification of all service components used on the service & revalidation of the equipment, Certification of all test equipment used to record the data along with current calibration certificates for all equipment.

Recorded in a document that is acceptable for the requirements.

Once this has been verified that all the requirements have been met then this could prove to be best value.

If all parameters are not met then we do not have a level playing field?

Are the national contracts worth the effort put in to become an approved

supplier?

Paragraph 3

The most recent audit took place in February, with the outcome being a recommendation for the continuation of the certification.

The audit was carried out for a second time within the endoscopy unit due to the failings identified within the endoscopy department in the previous audit.

The unit had to report an incident to MHRA for the use of non-validated chemicals being inserted into machines to perform high-level disinfection processes on endoscopes for use in patients in June 2017 and a subsequent IRIC investigation took place and found the unit at fault for all matters concerned.

After this investigation was completed the unit then proceeded to do this 2 further times but choose to ignore the incidents.

The head of decontamination, the decontamination manager, quality & safety manager, Health facilities Scotland authorising engineer where all informed but all choose not to respond.

Email chain can be provided.

Cabinet Secretary for Health and Sport
Shona Robison MSP

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Mr Alex Neil MSP
The Scottish Parliament
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Our ref: 2018/0009997
April 2018

I am grateful for your further letter in connection with decontamination services within NHS Grampian.

Managers of the decontamination services at NHS Grampian are fully aware of the technical requirements of the work in question, and have given reassurances that they will not compromise on those. The Health Board is investing in the skill-set of in-house staff and is confident that staff will achieve the required certification as planned.

As I stated in my previous letter, NHS Grampian has contracted a suitably qualified and experienced third-party to provide interim support, where required, during the transition period. The Health Board confirms that these arrangements are in full compliance with the NHS Scotland framework, as agreed by the relevant commodity manager at NHS National Procurement.

Finally, in relation to the BSI audit, the Health Board again states that this was carried out in February 2018 and continuing certification has been confirmed. The Health Board has also provided reassurance that it routinely reports all potentially adverse incidents to the Incident Reporting and Investigating Centre as standard, and these are further reported to the Medicines and Healthcare Products Regulatory Agency where appropriate. The Health Board also confirms that any potentially adverse events relating to the decontamination services have been fully reported, investigated, and concluded satisfactorily.

I hope this is helpful.

SHONA ROBISON

Correspondence with John Swinney, May 2018

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

Cabinet Secretary for Health and Sport
Shona Robison MSP

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Mr John Swinney MSP
The Scottish Parliament
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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 – PERSONAL INFORMATION (S38(1)(B)]'s 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 – PERSONAL INFORMATION (S38(1)(B)].

The adverse events that [REDACTED – PERSONAL INFORMATION (S38(1)(B)] 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 – PERSONAL

INFORMATION (S38(1)(B)] 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 – PERSONAL INFORMATION (S38(1)(B)] and also our current service arrangements. This was primarily in response to [REDACTED – PERSONAL INFORMATION (S38(1)(B)]'s 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 indicates that the chance of any actual patient harm associated with the issues raised by [REDACTED – PERSONAL INFORMATION (S38(1)(B)] was very low indeed.

I am aware that the Health Board offered to meet [REDACTED – PERSONAL INFORMATION (S38(1)(B)] on 14 May in order to attempt to move forward from the present situation, though I understand that [REDACTED – PERSONAL INFORMATION (S38(1)(B)] 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 – PERSONAL INFORMATION (S38(1)(B)]'s position, and explore how a viable supplier relationship might be re-established and sustained, and I would hope that [REDACTED – PERSONAL INFORMATION (S38(1)(B)] feels in a position to accept the offer.

SHONA ROBISON

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Mr John Swinney MSP
The Scottish Parliament
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Your ref: JS3471CS
Our ref: 2018/0024778
August 2018

Thank you for your letter of 13 July, on behalf of your constituents [REDACTED – PERSONAL INFORMATION (S38(1)(B)], concerning decontamination services at NHS Grampian.

The Health Board has confirmed to me that the specific issue raised by [REDACTED – PERSONAL INFORMATION (S38(1)(B)] relates, in this instance, to its use of the disinfectant *neodisher endo® SEPT PAC* versus *neodisher® Septo PAC*, both produced by the manufacturer Dr Weigert GmbH & Co. KG. Dr Weigert is an established supplier of specialist detergents and disinfectants to Wassenburg, one of NHS Grampian's key decontamination equipment suppliers. Dr Weigert also provides products through wholesalers to the NHS.

Dr Weigert formally advised customers of a brand name change on 15 March 2013, with *neodisher® Septo PAC* becoming *neodisher endo® SEPT PAC*. The Health Board confirms that, in doing so, the company clearly indicating that the chemical had not changed and only the volume provided in each canister was different. This change was to improve user safety.

The original product (*neodisher® Septo PAC*) had been 'type tested' by NHS Grampian's equipment supplier (Wassenburg) and therefore the identical chemical product, used in exactly the same way, has been accepted as being equally effective. Dr Weigert's advice note of 15 March 2013 also says "this customer information can be added to validation documents, if required" which is consistent with no additional type-testing or validation being needed.

The Health Board further confirms that updated product information was provided for *neodisher endo® SEPT PAC* in November 2016, which explicitly says the product is suitable for the decontamination equipment used by NHS Grampian (Wassenburg WD 440 endoscope washers).

Given the above, NHS Grampian does not agree with [REDACTED – PERSONAL INFORMATION (S38(1)(B)]'s assertion that the use of *neodisher endo® SEPT PAC* is an 'incident' with potential patient-safety, stating that it has the disinfectant manufacturer's written assurance that this is the same chemical, only in a lesser-filled canister. Although noting the [REDACTED – PERSONAL INFORMATION (S38(1)(B)]' comments, given the assurances the Health Board has had from the equipment manufacturer, the chemical supplier and its independent Authorising Engineer from Health Facilities Scotland, it is confident that this does not indicate any risk to patients.

With respect to the [REDACTED – PERSONAL INFORMATION (S38(1)(B)]' suggestion that Mr Payne (Deputy Director for Facilities and Estates) was not aware of the alleged incident or [REDACTED – PERSONAL INFORMATION (S38(1)(B)]'s concerns when they met in early June, the Health Board is aware that the [REDACTED – PERSONAL INFORMATION (S38(1)(B)]' original comments, made around October 2017 on this issue, had been sent to a number of local and national-level NHS managers and specialists in decontamination. There was consensus and confidence at that time that there was no incident or patient risk and these suggestions were accordingly not escalated further.

By way of an additional level of assurance, the Health Board also points out that equipment and decontamination processes are subject to regular efficacy testing, and it has passed annual tests using the re-branded chemical. These tests are carried out by Health Facilities Scotland to provide a level of independent assurance.

In light of the e-mail from Dr Weigert ([REDACTED – PERSONAL INFORMATION (S38(1)(B)], Business Development Manager) to [REDACTED – PERSONAL INFORMATION (S38(1)(B)], NHS Grampian has made direct enquiries to Dr Weigert and Wassenburg. Further, it will raise a national-level incident report (IRIC) to formally address the need for clarification and to obtain additional assurance both for itself and for other Health Boards.

I hope this helps to clarify the position.

JEANE FREEMAN

Cabinet Secretary for Health and Sport
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Mr John Swinney MSP
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Your ref: JS3471CS
Our ref: 2018/0024778
August 2018

Thank you for your letter of 13 July, on behalf of your constituents [REDACTED – PERSONAL INFORMATION (S38(1)(B)], concerning decontamination services at NHS Grampian.

The Health Board has confirmed to me that the specific issue raised by [REDACTED – PERSONAL INFORMATION (S38(1)(B)] relates, in this instance, to its use of the disinfectant *neodisher endo® SEPT PAC* versus *neodisher® Septo PAC*, both produced by the manufacturer Dr Weigert GmbH & Co. KG. Dr Weigert is an established supplier of specialist detergents and disinfectants to Wassenburg, one of NHS Grampian's key decontamination equipment suppliers. Dr Weigert also provides products through wholesalers to the NHS.

Dr Weigert formally advised customers of a brand name change on 15 March 2013, with *neodisher® Septo PAC* becoming *neodisher endo® SEPT PAC*. The Health Board confirms that, in doing so, the company clearly indicating that the chemical had not changed and only the volume provided in each canister was different. This change was to improve user safety.

The original product (*neodisher® Septo PAC*) had been 'type tested' by NHS Grampian's equipment supplier (Wassenburg) and therefore the identical chemical product, used in exactly the same way, has been accepted as being equally effective. Dr Weigert's advice note of 15 March 2013 also says "this customer information can be added to validation documents, if required" which is consistent with no additional type-testing or validation being needed.

The Health Board further confirms that updated product information was provided for *neodisher endo® SEPT PAC* in November 2016, which explicitly says the product is suitable for the decontamination equipment used by NHS Grampian (Wassenburg WD 440 endoscope washers).

Given the above, NHS Grampian does not agree with [REDACTED – PERSONAL INFORMATION (S38(1)(B)]'s assertion that the use of *neodisher endo® SEPT PAC* is an 'incident' with potential patient-safety, stating that it has the disinfectant manufacturer's written assurance that this is the same chemical, only in a lesser-filled canister. Although noting the [REDACTED – PERSONAL INFORMATION (S38(1)(B)]' comments, given the assurances the Health Board has had from the equipment manufacturer, the chemical supplier and its independent Authorising Engineer from Health Facilities Scotland, it is confident that this does not indicate any risk to patients.

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By way of an additional level of assurance, the Health Board also points out that equipment and decontamination processes are subject to regular efficacy testing, and it has passed annual tests using the re-branded chemical. These tests are carried out by Health Facilities Scotland to provide a level of independent assurance.

In light of the e-mail from Dr Weigert ([REDACTED – PERSONAL INFORMATION (S38(1)(B)], Business Development Manager) to [REDACTED – PERSONAL INFORMATION (S38(1)(B)], NHS Grampian has made direct enquiries to Dr Weigert and Wassenburg. Further, it will raise a national-level incident report (IRIC) to formally address the need for clarification and to obtain additional assurance both for itself and for other Health Boards.

I hope this helps to clarify the position.

JEANE FREEMAN

The Scottish Parliament
Pàrlamaid na h-Alba

John Swinney MSP
Member of the Scottish Parliament for Perthshire North

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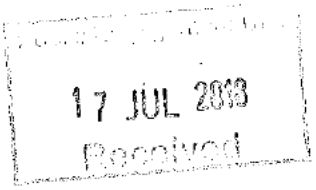


Our Ref: JS3471CS

13 July 2018

Dear Cabinet Secretary,

Re: Medical Devices UK

I wrote to Shona Robison on 17th May 2018 regarding the concerns of my constituents, [redacted] and [redacted], who are Directors of Medical Devices UK.

Shona Robison replied to me on 13th June 2018 and I have discussed this matter with my constituents who remain concerned that the contents of the reply that came from the Health Secretary.

In the reply of 13th June, Shona Robison stated that 'all potential patient safety concerns have been reviewed satisfactorily'. My constituent disputes the veracity of that statement as the process that was applied was a non validated process so there is no way in which the concerns could have been addressed satisfactorily.

When my constituents discussed the incident that took place in September 2017, in NHS Grampian, with Mr [redacted] he was unaware there was an incident which had caused difficulty and concern in September 2017.

My constituent is concerned that NHS Grampian is not properly investigating this issue. I enclose two e mails, one from the manufacturer of the equipment which indicates that a particular fluid that was used has not been tested by the manufacturer despite the fact that my constituent has been told that it has been approved by the manufacturer.

Parliamentary Office: The Scottish Parliament, Edinburgh, EH99 1SP Tel: 0131 348 5717
Constituency Office: 17-19 Leslie Street, Blairgowrie, PH10 6AH Tel: 01250 876 576
email: john.swinney.msp@parliament.scot www.johnswinney.scot

I cite these two examples to illustrate that my constituent really is dissatisfied that NHS Grampian is not properly and fully investigating this matter and providing quality information to the Scottish Governnment to address these concerns.

I would be grateful if you would look further into this matter and ensure that the concerns of my constituent are fully and properly addressed.

Yours sincerely,

John Swinney, MSP

Letter dictated by Mr Swinney and signed in his absence

Enc

From: [redacted]
Subject: RE: re telephone conversation
Date: 14 June 2018 21:31
To: [redacted]
Cc: [redacted]

Good evening [redacted]

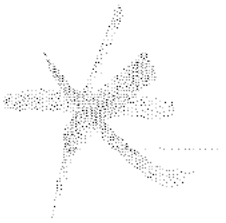
I can confirm that neodisher endo® SEPT PAC has not been type tested, validated or approved for use in Wassenburg machines.

Best regards,

Applies to Kyle Kerr.

[redacted]
Business Development Manager

Mobile: [redacted]



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From: [redacted]
Sent: 14 June 2018 16:14
To: [redacted]
Subject: re telephone conversation

Hi Lee,

I hope you are well.

Re previous discussion in regard to chemical changeover.

I am contacting you because I have had an email communication sent to me, within the email the below statement has been made.
Can you please confirm if this is the case and that this product has been **Type tested for Wassenburg equipment** this customer wants to install this on machines without type testing data or PQ testing.

This was discussed with the Decontamination Service management that endo SEPT PAC was a controlled name change to our existing disinfecting chemical (Septo PAC) made in 2013, with exactly the same composition and operating parameters. The apparent difference between the two brand-names is the volume in the canister.
The chemical is supplied by the same company (Dr Weigert) and it's use is approved by Wassenburg.

I will await your response before I reply I would like to be in a position where I can inform this customer the correct information.

Best Regards

[redacted]

[redacted]
Medical Devices UK Ltd
[redacted]
info@medicaldevicesuk.co.uk
www.medicaldevicesuk.co.uk

Medical Devices

Cabinet Secretary for Health and Sport
Jeane Freeman MSP

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Mr John Swinney MSP
The Scottish Parliament
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Your ref: JS3471CS
Our ref: 2018/0024778
14 August 2018

Thank you for your letter of 13 July, on behalf of your constituents [redacted] concerning decontamination services at NHS Grampian.

The Health Board has confirmed to me that the specific issue raised by [redacted] relates, in this instance, to its use of the disinfectant *neodisher endo® SEPT PAC* versus *neodisher® Septo PAC*, both produced by the manufacturer Dr Weigert GmbH & Co. KG. Dr Weigert is an established supplier of specialist detergents and disinfectants to Wassenburg, one of NHS Grampian's key decontamination equipment suppliers. Dr Weigert also provides products through wholesalers to the NHS.

Dr Weigert formally advised customers of a brand name change on 15 March 2013, with *neodisher® Septo PAC* becoming *neodisher endo® SEPT PAC*. The Health Board confirms that, in doing so, the company clearly indicating that the chemical had not changed and only the volume provided in each canister was different. This change was to improve user safety.

The original product (*neodisher® Septo PAC*) had been 'type tested' by NHS Grampian's equipment supplier (Wassenburg) and therefore the identical chemical product, used in exactly the same way, has been accepted as being equally effective. Dr Weigert's advice note of 15 March 2013 also says "this customer information can be added to validation documents, if required" which is consistent with no additional type-testing or validation being needed.

The Health Board further confirms that updated product information was provided for *neodisher endo® SEPT PAC* in November 2016, which explicitly says the product is suitable

for the decontamination equipment used by NHS Grampian (Wassenburg WD 440 endoscope washers).

Given the above, NHS Grampian does not agree with [redacted]s assertion that the use of *neodisher endo® SEPT PAC* is an 'incident' with potential patient-safety, stating that it has the disinfectant manufacturer's written assurance that this is the same chemical, only in a lesser-filled canister. Although noting the [redacted]' comments, given the assurances the Health Board has had from the equipment manufacturer, the chemical supplier and its independent Authorising Engineer from Health Facilities Scotland, it is confident that this does not indicate any risk to patients.

With respect to the [redacted]' suggestion that Mr Payne (Deputy Director for Facilities and Estates) was not aware of the alleged incident or Mr [redacted]'s concerns when they met in early June, the Health Board is aware that the [redacted]' original comments, made around October 2017 on this issue, had been sent to a number of local and national-level NHS managers and specialists in decontamination. There was consensus and confidence at that time that there was no incident or patient risk and these suggestions were accordingly not escalated further.

By way of an additional level of assurance, the Health Board also points out that equipment and decontamination processes are subject to regular efficacy testing, and it has passed annual tests using the re-branded chemical. These tests are carried out by Health Facilities Scotland to provide a level of independent assurance.

In light of the e-mail from Dr Weigert ([redacted], Business Development Manager) to [redacted], NHS Grampian has made direct enquiries to Dr Weigert and Wassenburg. Further, it will raise a national-level incident report (IRIC) to formally address the need for clarification and to obtain additional assurance both for itself and for other Health Boards.

I hope this helps to clarify the position.

JEANE FREEMAN