The Scottish Parliament
Pàrlamaid na h-Alba

PUBLIC PETITIONS COMMITTEE

AGENDA

12th Meeting, 2014 (Session 4)

Tuesday 17 June 2014

The Committee will meet at 9.30 am in the Robert Burns Room (CR1).

1. **Consideration of a current petition:** The Committee will consider—

   PE1517 by Elaine Holmes and Olive McIlroy, on behalf of the Scottish Mesh Survivors - "Hear Our Voice" campaign, on polypropylene mesh medical devices

   and take evidence from—

   Alex Neil, Cabinet Secretary for Health and Wellbeing, and Dr Frances Elliot, Deputy Chief Medical Officer, Scottish Government.

2. **Consideration of new petitions:** The Committee will consider—

   PE1521 by George Eckton and Jane O'Donnell on no more Page 3 in the Scottish Sun and Scottish Parliament

   and take evidence from—

   George Eckton, and Jane O'Donnell;

   and will then consider—

   PE1518 by George M Chalmers on meaningful public consultation within the Scottish planning system

   and take evidence from—

   George M Chalmers;

   and will then consider—

PE1519 by John F Robins, on behalf of the Save Our Seals Fund, on saving Scotland's seals

and take evidence from—

John F Robins, Secretary, Save Our Seals Fund;

and will then consider—

PE1520 by Mary Laing on unrestricted freedom to build on plots of up to 1 acre.

3. **Inquiry into tackling child sexual exploitation in Scotland:** The Committee will consider a response from the Scottish Government.

4. **Consideration of current petitions:** The Committee will consider—

PE1408 by Andrea MacArthur on the updating of Pernicious Anaemia/Vitamin B12 Deficiency understanding and treatment;
PE1480 by Amanda Kopel, on behalf of the Frank Kopel Alzheimer's Awareness Campaign, on Alzheimer's and dementia awareness;
PE1492 by Alan Kennedy on co-location of GP practices and community pharmacies;
PE1505 by Jackie Watt on awareness of Strep B in pregnancy and infants;
PE1503 by Mike Burns, on behalf of Average Speed Cameras on the A9 are not the Answer, on a review of A9 speed camera proposals.

Anne Peat
Clerk to the Public Petitions Committee
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The Scottish Parliament
Edinburgh
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The following papers are attached for this meeting—

Agenda item 1

PE1517	Note by the Clerk	PPC/S4/14/12/1
PRIVATE PAPER		PPC/S4/14/12/2 (P)

Agenda item 2

PE1521	Note by the Clerk	PPC/S4/14/12/3
Petitioner Letter of 5 June 2014		PE1521/A
PE1518	Note by the Clerk	PPC/S4/14/12/4
PE1519	Note by the Clerk	PPC/S4/14/12/5
PE1520	Note by the Clerk	PPC/S4/14/12/6

Agenda item 3

Scottish Government response of 30 April 2014

Agenda item 4

PE1408	Note by the Clerk	PPC/S4/14/12/7
British Committee for Standards in Haematology Email of 12 May 2014		PE1408/P
Scottish Government Letter of 10 June 2014		PE1408/Q
PE1480	Note by the Clerk	PPC/S4/14/12/8
Scottish Government Letter of 19 May 2014		PE1480/E
PE1492	Note by the Clerk	PPC/S4/14/12/9
Petitioner Letter of 5 June 2014		PE1492/F
PE1505	Note by the Clerk	PPC/S4/14/12/10
UK National Screening Committee Letter of 24 April 2014		PE1505/A
Scottish Government Letter of 28 April 2014		PE1505/B
Petitioner Email of 10 June 2014		PE1505/C
PE1503	Note by the Clerk	PPC/S4/14/12/11
A9 Safety Group Letter to the Petitioner of 9 May 2014		PE1503/O
Petitioner Letter to the A9 Safety Group of 22 May 2014		PE1503/P
A9 Safety Group Letter to the Petitioner of 9 June 2014		PE1503/Q

Public Petitions Committee

12th Meeting, 2014 (Session 4), Tuesday 17 June 2014

PE1517 on Polypropylene Mesh Medical Devices

Note by the Clerk

PE1517 – Lodged 1 May 2014
Petition by Elaine Holmes and Olive McIlroy, on behalf of the Scottish Mesh Survivors – "Hear Our Voice" campaign, Calling on the Scottish Parliament to urge the Scottish Government to:
1. Suspend use of polypropylene Transvaginal Mesh (TVM) procedures;
2. Initiate a Public Inquiry and/or comprehensive independent research to evaluate the safety of mesh devices using all evidence available, including that from across the world;
3. Introduce mandatory reporting of all adverse incidents by health professionals;
4. Set up a Scottish Transvaginal Mesh implant register with view to linking this up with national and international registers;
5. Introduce fully Informed Consent with uniformity throughout Scotland's Health Boards; and
6. Write to the MHRA and ask that they reclassify TVM devices to heightened alert status to reflect ongoing concerns worldwide.
Link to petition webpage

Purpose

1. The Committee agreed to invite the Cabinet Secretary for Health and Wellbeing to give evidence after hearing from the petitioners at the last meeting. The Cabinet Secretary is here today. Following today's meeting the Committee is invited to consider what action it wishes to take in relation to the petition.

Background – the following information is taken from the SPICe briefing

The use of Transvaginal Mesh

2. Transvaginal mesh (TVM) can be used in pelvic organ prolapse (POP), and transvaginal tapes (TVT) can be used in the treatment of stress urinary incontinence (SUI).

3. For both conditions there are non-surgical interventions, though it may be necessary to consider surgery in certain cases. However, traditional surgery techniques are associated with a range of short and long term complications[1]. Indeed, in terms of surgery for POP, there is a 20%-30% failure rate from primary prolapse surgery and women may need second and subsequent procedures to address prolapse recurrence. As a result, synthetic (non-absorbable) and biological (absorbable) meshes were introduced into surgery as

[1] Scottish Government (July 2013) 'Letter from the Chief Medical Officer to NHS Boards: Transvaginal mesh' (p 3)

supporting materials in surgical treatments.[2] It is estimated that about 1,500 TVT for SUI and 350 TVM for POP are implanted annually in Scotland[3].

Regulating the safety of Transvaginal Mesh Products

4. TVM and TVT products are medical devices. The regulation of medical devices (including a determination of safety before a CE mark is applied and ongoing vigilance monitoring thereafter) is a matter reserved to the UK Parliament. Regulation of Medical Devices is governed through a number of EU Directives transposed into UK law by regulations. The Medicines and Healthcare Products Regulatory Agency (MHRA) is the competent authority in this area for the UK. A short description of the regulatory system is provided in Appendix 1.

5. The petition calls for the Scottish Government to initiate a Public Inquiry and/or comprehensive independent research to evaluate the safety of mesh devices. Whilst the Scottish Government could initiate the latter, under section 28 of the Inquiries Act 2005, Scottish Ministers do have the powers to set up a public inquiry, but only where the matter concerned is devolved.

6. After a medical device has had a CE mark applied, there should be on-going vigilance monitoring including any adverse incidents that are reported on the use of a device. The MHRA has an overarching role in this but in Scotland adverse incidents are handled by Health Facilities Scotland. Its role is outlined in Appendix 2. HFS has received 14 adverse incident reports concerning TVM and TVT between 24 December 2012 and 27 March 2014[4].

Current UK guidance and evidence on the safety of TVM and TVT

7. The petitioner makes note of the recent decision by the United States Food and Drug Administration (FDA) to issue two proposed orders, which if approved, "will require manufacturers to provide premarket clinical data to demonstrate a reasonable assurance of safety and effectiveness for surgical mesh used to treat transvaginal POP repair". This followed a number of reviews by the FDA which "identified clear risks associated with surgical mesh for the transvaginal repair of pelvic organ prolapse".[5] It is important to note that the proposed order does not cover surgical mesh for SUIs and a number of other conditions.

8. The FDA's decision has led to calls for regulators at European and UK levels to review their guidance. The current MHRA view[6] is that whilst it has received a number of reports of complications arising from the use of TVM for POP, it has "no evidence the devices themselves have inherent problems that would necessitate consideration of any steps up to and including consideration of

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[2] Medicines and Healthcare Products Regulatory Agency (Online) 'Vaginal mesh for pelvic organ prolapse'

[3] Scottish Government (July 2013) 'Letter from the Chief Medical Officer to NHS Boards: Transvaginal mesh' (p 3)

[4] Scottish Government. Personal communication 28 May 2014

[5] US Food and Drug Administration (April 2014) 'FDA issues proposals to address risks associated with surgical mesh for transvaginal repair of pelvic organ prolapse'

[6] As outlined in MHRA (Online) Vaginal mesh for pelvic organ prolapse

product removal from the market". However, due to concerns being raised, the MHRA commissioned The University of York's Health Economics Consortium to undertake an independent review of the safety and of any adverse effects associated with TVM for POP and TVT for SUI. The report was published in November 2012. This research confirmed that for TVT for SUI the rates of adverse events were low, but that for TVM for POP the rates of adverse events were higher and this is a factor which patients considering surgery will wish to take into account in discussion with their surgeons. [7]

9. The Scottish Government's advice concerning safety is discussed in the Chief Medical Officer's letter to NHS Boards from July 2013.

Determining whether a medical device is used in the NHS

10. Whilst the regulation of medical devices is reserved, whether or not a product is used in the NHS in Scotland is a devolved matter. However, unlike in the case of newly licensed medicines, newly CE marked applied medical devices are not routinely appraised for use in the NHS, though it is possible to request an assessment or apply evidence from elsewhere. For example, NHSScotland is a partner in the National Institute for Health and Clinical Excellence's interventional procedures programme which has provided guidance on the use of mesh in certain POP operations[8].

11. Whether a particular technology is used is a matter for individual clinicians and NHS Boards taking account of evidence and guidance. There are structures within the NHS in Scotland that can provide advice, including the Scottish Health Technologies Group[9], though it has not undertaken any work on TVM or TVT.

12. The petitioner calls on the Scottish Government to suspend the use of TVM procedures. The Scottish Government could issue guidance in this regard. However, in recent Parliamentary Questions, its position is for the regulatory bodies at UK and EU level to consider the evidence concerning the use of these products. Recently, the Minister for Public Health, Michael Matheson MSP stated: "…if there is any change to the guidance or a recommendation is made by the MHRA or the European Community, the Government will act swiftly on that"[10].

Informed consent

13. Another key part of the petition concerns ensuring that patients give informed consent when they are offered surgery involving TVM. In 2009, the Scottish Public Services Ombudsman upheld a complaint by a patient who had TVM

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[7] Scottish Government (July 2013) 'Letter from the Chief Medical Officer to NHS Boards: Transvaginal mesh' (p 5-6)

[8] IPG267: Surgical repair of vaginal wall prolapse using mesh (June 2008) and IPG282: Insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair (January 2009)

[9] This is an advisory group that sits within Healthcare Improvement Scotland that provides advice on the evidence about the clinical and cost effectiveness of existing and new technologies that are likely to have significant implications for patient care in Scotland.

[10] S4T-00695

surgery without giving proper consent. The Scottish Government has outlined what it expects as regards obtaining proper consent from patients[11]. Included is a reference to two of the health care principles (Schedule) of the Patient's Rights (Scotland) Act 2011, namely: patients participate as fully as possible in decisions relating to the patient's health and wellbeing; and, patients are provided with such information and support as is necessary to enable them to participate in accordance with paragraph 12 and in relation to any related processes (general or specific). Further information is provided in the Health Rights Information Scotland leaflet 'Consent – it's your decision'.

14. Specific for patients who are being considered for mesh or tape surgery, the MHRA has outlined the questions patients should ask of their doctor, as well as links to professional body guidance for TVM and TVT.

Scottish Government Action

15. In addition to the actions discussed above, the Scottish Government[12] has set up an expert working group, chaired by the Deputy Chief Medical Officer, to address the issues affecting women who have undergone transvaginal mesh surgery. The group is developing:

    - A revised patient information and consent booklet for NHSScotland, to be given to women considering undergoing a synthetic vaginal mid-urethral tape procedure for stress urinary incontinence.
    - New care pathways for those women who decide to go ahead with a mesh procedure and for those who have suffered complications.
    - A strengthened process for adverse incident reporting.

16. The Cabinet Secretary for Health and Wellbeing has also written to the MHRA and the European Commission asking that they urgently consider the United States FDA's proposed reclassification of surgical mesh for the treatment of pelvic organ prolapse.[13] Other actions have included:

    - Undertaking work on the feasibility of recording the type of medical device used in treatment, and how it was used, on a patient's electronic record, to assist in identifying clearer picture of the number of patients who may be affected should problems occur with a particular implant in the future.[14]
    - Undertaking discussions with stakeholders on the establishment of an implant registry.[15]

Scottish Parliament Action

17. There have been a number of Parliamentary Questions on the issue of mesh medical devices lodged since the beginning of May this year. In addition to the

[11] S4W-18278
[12] S4W-20948
[13] S4T-00695
[14] S4T-00695
[15] S4W-18271

action outlined above, the Cabinet Secretary for Health and Wellbeing has also subsequently stated the Scottish Government's intention to write again to Medical Directors, as well as NHS Inform, once the expert working group has concluded its work.

18. The petition and the call to suspend the use of polypropylene mesh implants pending an inquiry into their safety were raised at First Minister's Question Time on 5 June 2014, following the Committee's previous meeting. In his response, the First Minister stated the Scottish Government's intention to act "in conjunction with the other health departments across these islands."

Committee Consideration

19. Prior to the petition being considered at committee, Tom Joyce, Professor of Orthopaedic Engineering at Newcastle University, submitted a letter in which he argues that when there are major concerns over the use of medical implants, their use should stop. The petitioner also provided a copy of a letter from Dr Michael Margolis to the Cabinet Secretary for Health and Wellbeing, in which he highlights his experience of treating women with TVM implants and argues that their use should stop.

20. The Committee considered the petition for the first time on 3 June 2014 and heard evidence from the petitioners and Marion Scott of the Sunday Mail. The Committee agreed to write to the Scottish Government, the Medicines Healthcare Products Regulatory Agency, NHS National Services Scotland, the European Commission, the Royal College of Surgeons of Edinburgh, the British Medical Association Scotland and NHS boards. The Committee also agreed to invite the Cabinet Secretary for Health and Wellbeing to give evidence.

Action

21. Following the evidence session with the Cabinet Secretary, the Committee is invited to agree what action it wishes to take in respect of the petition. The Committee may wish to defer further consideration until the written responses have been received.

Appendix 1: The regulation of medical devices

Transvaginal Mesh (TVM) products are regulated as medical devices. The term "medical devices" covers a range of products, from non-invasive support products such as bandages, to implanted devices such as pacemakers breast implants and TVM. It is estimated that there are over 90,000 types of medical devices on the market in the UK[16]. Regulation includes establishing the safety of the product both prior to market authorisation (i.e. CE marking) and thereafter, and is a reserved matter to the UK Parliament. Regulation is governed through a number of EU Directives, transposed into UK law through regulations.

Medical devices are classified by the Directives according to the level of risk they pose to the patient. There are four classes of risk (I, IIa, IIb, and III), with the lowest risk devices (e.g. stethoscopes) falling into Class I, and products such as dental fillings being defined as Class IIa. Medical implants, such as TVM) are always classified as Class IIb or III, because they are placed within the body, require invasive surgery, and are designed to be in continuous use. As a result these products must be regulated in a particular way (see Figure 1).

The safety of TVM and other invasive medical devices is assessed by an independent third party organisation (or "notified body") of which there are around 80 across Europe. These bodies are appointed and audited by the competent regulatory authority in each member state, which is the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK. The role of the notified body is to determine whether a particular medical device meets the relevant regulatory requirements and, whether, when used as intended, it works properly and is acceptably safe. A manufacturer can select any notified body across Europe irrespective of location, provided that their field of expertise covers the device being considered. Once a CE mark is applied the medical device can be sold in all EU countries without further controls.

Following market authorisation, the notified body should ensure that the manufacturer adheres to quality systems and provides it with agreed information. The notified body may also pay unannounced visits to the manufacturer and carry out or ask for tests in order to check the quality system is working properly. A notified body may suspend or withdraw a CE certificate, place restrictions on it or trigger an intervention from the competent authority. In such circumstances the notified body must inform the competent authority in its own country, and the competent authority must inform other competent authorities and the European Commission of such action.

However, the device manufacturer is central to the vigilance and incident reporting system. Manufacturers must report certain adverse incidents to the relevant national competent authority (the competent authority where the incident has occurred, unless otherwise specified) for recording and evaluation.

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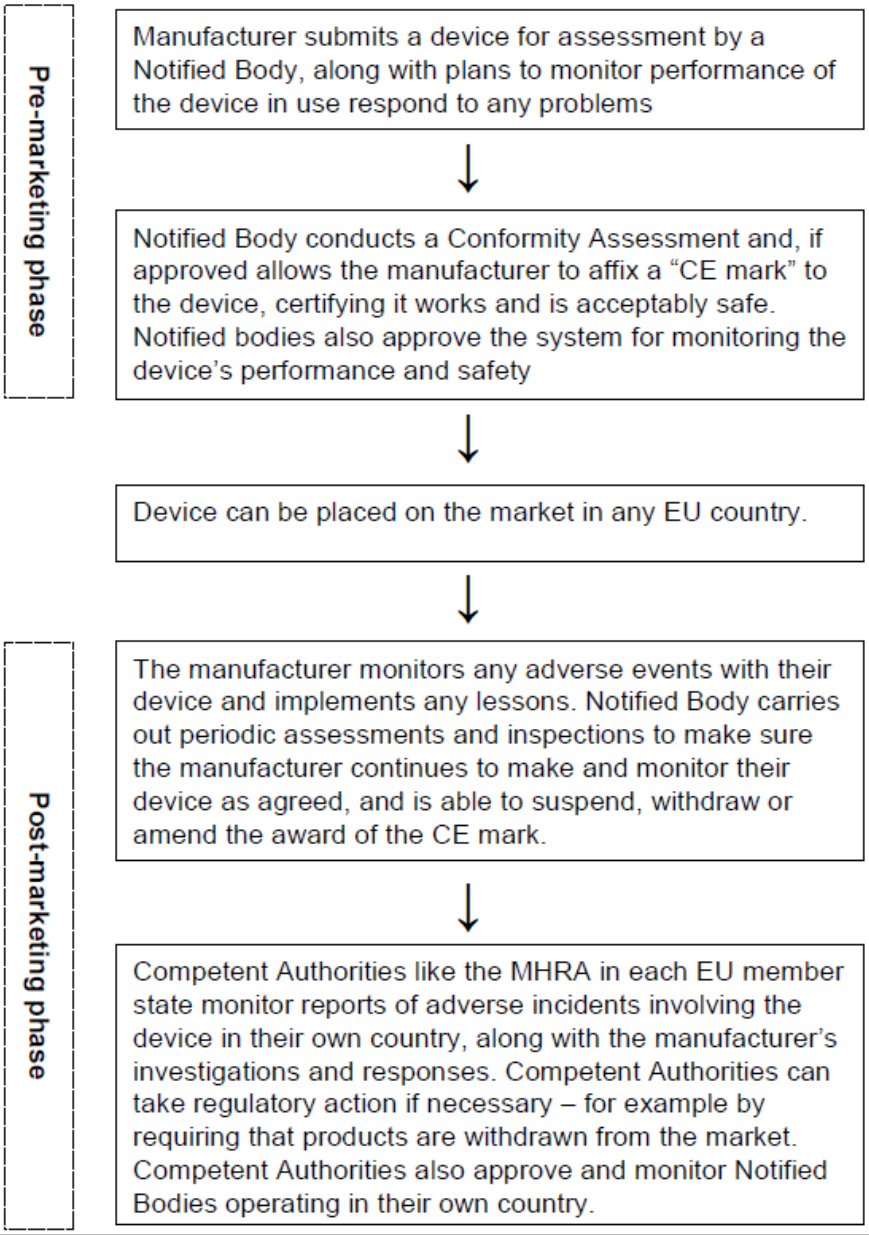
[16] Keogh, Sir Bruce (6 January 2012) 'Poly implant prostheses (PIP) breast implants: Interim report of the Expert group'

Figure 1: European medical device regulation – key stages in the process



Source: Earl Howe (2012) 'Poly Implant Prothèse (PIP) silicone breast implants: Review of the action of the MHRA and the Department of Health'

One of the roles of the competent authority is to establish a 'vigilance' programme in relation to post-market surveillance of the performance and safety of medical devices. In the UK this involves investigating both mandatory serious adverse event reports from manufacturers and adverse events reported voluntarily by healthcare professionals and members of the public. Adverse incidents in Scotland are handled by Health Facilities Scotland (a division of NHS National Services Scotland). Its role is outlined in Appendix 2. If adverse events are proved, the MHRA can take a series of actions including the removal of the CE mark, the recalling of faulty products and providing advice to the health service through Medical Device Alerts. Where

regulations are breached, the MHRA has the power to prosecute. It can also withdraw unauthorised / illegal products form the market.

The rationale for employing the notified body system for medical device regulation is because of the sheer size and breadth of the market for the products and the large number of new products that come onto the market. It is also seen as an efficient and flexible system.

However, over recent years there have been a number of concerns raised into the system, most notably following the PIP breast implants case. The European Commission published a proposed revision of the medical devices directives in September 2012. This has now been considered by the European Parliament, and now awaits consideration by the European Council. This was not a reaction to the PIP and other cases themselves, as the public consultation on it began in 2008, but it has since taken account of the issues in those cases.

Meanwhile in the UK, there have been a number of reviews into PIP and the regulatory system of medical devices, including:

- House of Commons Health Committee (March 2012) Sixteenth Report: PIP Breast Implants and regulation of cosmetic interventions [webpage includes link to the UK Government response]
- Earl Howe (May 2012) 'Poly Implant Prothèse (PIP) silicone breast implants: Review of the action of the MHRA and the Department of Health'
- House of Commons Science and Technology Committee (November 2012) Regulation of medical implants in the EU and UK [webpage includes link to the UK Government response]
- Review of the Regulation of Cosmetic Interventions Committee (April 2013) Review report

Appendix 2: The reporting of adverse incidents concerning medical devices in NHS Scotland

Adverse incidents reported through the NHS in Scotland are handled by the Incident Reporting and Investigation Centre (IRIC) at Health Facilities Scotland (HFS) is part of NHS National Services Scotland. HFS is responsible for receiving adverse incident reports from NHS Boards and Local Authorities in regards to equipment and facilities. Medical devices are included in the definition of health and social care equipment used by HFS.

In October 2009, the Scottish Government published new guidance, which outlines the role of HFS and its responsibilities (as well as the responsibilities of public bodies).

The role of HFS

IRIC is responsible for receiving adverse incident reports and co-ordinating investigations so that, as far as possible, root causes can be established and remedial action taken to prevent or reduce any identified risks.

The MHRA is responsible for the regulation of medical devices throughout the UK and for issuing Medical Devices Alerts (MDAs). HFS works closely with MHRA, and will notify MHRA of each adverse incident reported in Scotland and the results of any investigation. For example, HFS may identify a need for an MDA and will liaise with MHRA in their assessment of the need for and drafting of the alert. If a health professional or other person in Scotland was to report an incident directly to MHRA, then MHRA would send that to HFS to consider.

HFS also liaises with other UK Health Departments, NHS bodies and agencies on the safety of estates and facilities equipment. In particular, information is exchanged on adverse incidents reports and investigations. In relation to adverse incidents involving medical devices, HFS provides each NHS Board Equipment Co-ordinator (or risk manager) a list of reports sent to HFS by their organisation during the previous quarter, as well as a list of all investigations still in progress.

HFS also has a role in maintaining a list of Equipment Co-ordinators for all NHS Boards (as well as local authorities) and should be notified immediately of any change. HFS also runs a network to support the work of Equipment Co-ordinators and their organisations. This includes various events to promote the management of risk and equipment safety in each organisation and generally throughout Scotland.

NHS Board responsibilities

Under the 2009 guidance NHS Boards are responsible for ensuring all staff are aware of all relevant policies and procedures. The guidance outlines the role of the Equipment Coordinator, the duties for which include:

- ensuring managers and staff are aware of the procedures for reporting adverse incidents and for implementing safety advice
- monitoring all adverse incidents reports from within own organisation

- receiving emails from HFS notifying of alerts and bulletins, and cascading within own organisation
- monitoring internal cascade systems to ensure alerts are received, assessed and acted upon

Boards must also ensure there are clear written and policy procedures for the prompt recording of all adverse incidents, including:

- preserving evidence and keeping records
- informing the organisational Equipment Co-ordinator
- maintaining a central register for equipment incidents in each organisation

There must also be clear policies for receiving, assessing and implementing all alerts and bulletins sent by HFS and MHRA (see paragraph 6.2).

Reporting incidents to HFS

The policy for reporting adverse incidents by a clinician or NHS Board is set out in Chief Executive Letter CEL 43 (2009). However, there can be a number of reasons why an adverse incident has not be reported. This could be because it is not clear that an adverse incident has been caused by a fault with the device. Other factors include the condition of the patient at the time of the procedure and clinician error.
As regards the timing of reporting, some Boards may report incidents immediately while others may wait until they have collected evidence of a trend or undertaken their own investigation as to whether it is an issue with the device. There may also be differences within Boards by hospital and clinician.

Nevertheless, when it is believed that there may be an issue with a device, this should be reported to HFS. How an incident should be report to HFS is outlined in Annex B of the 2009 guidance.

Adverse events framework

Healthcare Improvement Scotland has provided a framework for the management of adverse events and is linking into the work on adverse incidents. The reports are available here

Reporting by clinicians

Clinicians cannot be compelled to report an incident. Why this is appears to be related to the fact that there may be reasons for the adverse incident that may not be related to the device itself.

However, non-reporting of an adverse incident concerning a medical device would contravene the standards laid down by the General Medical Council which regulates all doctors. The regulation of doctors is a reserved matter.

The principal document which lays out what is expected from a doctor is 'Good Medical Practice', which was updated this year. Contained in domain 2 concerning safety and quality, it states that to help keep patients safe a doctor must:

> "…report adverse incidents involving medical devices that put or have the potential to put the safety of a patient, or another at risk" (23c).

This is backed up by 'Good practice in prescribing and managing medicines and devices' guidance which came into effect in February 2013. Paragraphs 46 to 50 outline what doctors must do in reporting adverse incidents. The separate arrangements for Scotland are included.

The MHRA has undertaken work with professional medical bodies, Royal Colleges and others to encourage greater reporting of incidents by clinicians. The work that has been undertaken is outlined on pages 4 to 7 of a progress report MHRA published in June 2013.

The responsibility of manufacturers

The 2009 guidance notes that the alerts system is not a replacement for direct action by manufacturers, who have responsibilities under EU regulations to address safety issues concerning their devices. This is discussed further in Annex D of the guidance.

Public Petitions Committee

12th Meeting, 2014 (Session 4), Tuesday 17 June 2014

PE1521 on no more Page 3 in the Scottish Sun and Scottish Parliament

Note by the Clerk

PE1521 – Lodged 20 May 2014
Petition by George Eckton and Jane O'Donnell calling on the Scottish Parliament to urge the editorial team of the Sun and Scottish Sun to voluntarily remove the page 3 feature permanently.
Furthermore, until the Sun/Scottish Sun ceases its page 3 feature we request the Scottish Parliament no longer stock/sell The Sun or Scottish Sun newspaper given its objectification of women and gender stereotyping both seem at odds with the Scottish Parliament's equalities framework.

Link to petition webpage

Purpose

1. This is a new petition that the Committee is invited to consider and agree what action it wishes to take. The Committee has invited the petitioners to speak to the petition.

Background – the following information is taken from the SPICe briefing

2. The No More Page 3 campaign began in the summer of 2012 when Jessica Ennis won an Olympic gold medal, and yet the most prominent female image in The Sun was of a topless young woman on page 3. This frustrated Lucy Ann Holmes, who wrote to the then editor Dominic Mohan.

3. On the campaign website, Lucy reads extracts from her letter to Dominic Mohan, which requests that he 'drop the bare boobs' from the paper. She refers to Home Office statistics that 300,000 women are sexually assaulted and 60,000 women are raped each year, and questions the message that Page 3 sends out to society. The No More Page 3 campaign also has an online petition at Change.org that has achieved over 190,000 signatures (at 29 April 2014).

4. The campaign has received support from a number of organisations including: the National Assembly for Wales, UK Girlguiding, Mumsnet, the NUT and UNISON. Most recently, the Scottish Government has indicated its support, see below, as well as Police Scotland via Assistant Chief Constable Malcolm Graham.

5. In February 2013, Rupert Murdoch, in response to a tweet about Page 3 being old fashioned, suggested he was considering whether to remove Page 3 and replace it with a 'halfway house with glamorous fashionistas'.

6. David Cameron has said he would not back a ban on Page 3[1] and in response to a question from Caroline Lucas MP about removing The Sun from the parliamentary estate until Page 3 has been removed, he said that members should be able to read all newspapers on the parliamentary estate[2].

7. This petition focuses the campaign on the Scottish Sun, and requests that the Scottish Parliament stops stocking the Sun until Page 3 has been removed as it is at odds with Parliament's equalities framework.

Scottish Parliament Action

8. A members' debate (S4M-07500), led by Jackie Bailie MSP, on the issues raised by the No More Page 3 campaign took place on 6 November 2013. The debate garnered cross-party support. Members debated the impact of Page 3 images on Scottish society and the connection between sexualised images and the reinforcement of sexist attitudes, harassment, abuse and violence towards women.

9. During the debate, Hanzala Malik MSP discussed boycotting newspapers like The Sun and continued, "I am sure that the Scottish Parliament ……will be one of the first organisations to take steps to cancel that newspaper if it continues to produce such photographs."[3]

The Scottish Parliament's Equalities Framework

10. In the foreword on the Equalities Framework, the Presiding Officer and the Clerk/Chief Executive state,

> "As one of the Parliament's four founding principles, equality is at the heart of our organisation. The SPCB recognises that everyone should have an equal opportunity and where there are barriers to participation, the SPCB will take steps to remove these so that no one is excluded from the activities of the Parliament and that people from all walks of life have the opportunity to engage, freely without discrimination, with its Members and staff."

11. There are two key drivers in the Framework:

- 'The importance of having a culture where everyone feels valued and respected and can contribute freely without fear of being judged because of a personal characteristic'.
- 'The need to deliver accessible services, by recognising the diversity of people's needs so that everyone can experience, and take part in the activities of the Parliament'.

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[1] The Guardian (22 July 2013) 'Cameron refuses to back ban on Sun's Page 3 topless images' and again, The Huffington Post (22 November 2013) 'David Cameron will not back ban on the Sun's Page 3 despite campaign against online porn'

[2] BBC news online (19 June 2013) 'Lucas and Cameron on Sun and page three pictures'

[3] Scottish Parliament *Official Report 6 November 2013* (col 24135-24136)

Scottish Government Action

12. The Scottish Government has sent a letter of support to the No More Page 3 campaign, signed by an official (March 2014).

Violence against women and girls

13. During the Scottish Parliament debate, Shona Robison, the Minister for Commonwealth Games and Sport, said that the Scottish Government was developing a strategy for Scotland to tackle violence against women, that it would be the first such document in Scotland, "and it will shape the way in which we tackle violence against women in the years ahead."[4] An outline of the strategy to address Violence Against Women and Girls (VAWG) was published on 17 January 2014, with a view to publishing the strategy in the summer 2014.

Press regulation

14. During the debate on No More Page 3, Shona Robison made reference to press regulation. She stated:

> "We know that one of the principles enshrined in the new framework of press regulation is that it remains for newspapers themselves to determine their content. That framework has received cross-party support.
>
> The decision of the Privy Council to approve the royal charter on press regulation is an extremely welcome one and, following the Scottish Parliament's unanimous decision to support the charter earlier this year, we have secured amendments that ensure that it properly reflects Scottish circumstances.
>
> I am sure that everyone here would agree that getting the framework right for establishing an effective system of independent self-regulation of the press, including cultures and practices, is an important step forward. In my view, getting a framework that can properly respond to concerns about the portrayals of women in the press is the most important priority"[5].

15. The Royal Charter on the self-regulation of the press was published on 30 October 2013.

UK Government

16. The UK Government commissioned Dr Linda Papadopoulos to research the Sexualisation of young people. This report is often cited as showing a connection between the portrayal of sexualised images with violence towards women and girls. It refers to existing research when it concludes that 'sexualising children prematurely places them at risk of a variety of harms'. However, it also says that

[4] Scottish Parliament *Official Report 6 November 2013* (col 24139)
[5] Ibid. (col 24138)

further empirical evidence is needed from large scale longitudinal studies that would look at the effects on boys and girls across their development. The report has received some criticism for lacking empirical evidence and for not defining the term 'sexualisation'[6].

UN Commission on the Status of Women

17. The petitioners refer to the UN Commission on the Status of Women and its latest report (March 2014) on the implementation of the Millennium Development Goals for women and girls. The report states that, "almost 15 years after the Millennium Development Goals were adopted, no country has achieved equality for women and girls and significant levels of inequality between women and men persist…"

18. Specific reference is made to paragraph B (xx):

> "Recognise the important role the media can play in the elimination of gender stereotypes, and to the extent consistent with freedom of expression, increase the participation and access of women to all forms of media, and encourage the media to increase public awareness of the Beijing Platform for Action, the Millennium Development Goals, gender equality and the empowerment of women and girls".

UN Special Rapporteur

19. Rashida Manjoo, UN Special Rapporteur, has said that sexism in the UK is more 'in your face' than in other countries and raised concerns about the portrayal of women in the media (BBC news online 15 April 2014[7]).Manjoo said that there was a 'more visible presence of sexist portrayals of women and girls' and a 'marketisation of women's and girls' bodies' in the UK, which was more pervasive than elsewhere (Guardian 15 April 2014[8]). The full report is expected to be published later this year, and presented to the UN human rights council in June 2015.

Research on sexual violence

20. The European Union Agency on Fundamental Rights has recently published research on violence against women across the EU. The research was based on face-to-face interviews with 42,000 women. For the UK it estimates that 8% of women (aged18-74) in the 12 months before interview had experienced physical and/or sexual violence. Using current population figures, this translates as 1.8 million women[9].

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[6] Robbie Duschinsky (2010) The 2010 Home Office review on the Sexualisation of Young People: A discursive policy analysis and Clarissa Smith (2010) Review: Papadopoulos, Linda: Sexualisation of Young People Review, in Journal of Audience and Reception Studies (Volume 7, Issue 1)

[7] BBC news online (15 April 2014) UN Special Rapporteur Rashida Manjoo says UK has 'sexist culture'

[8] Guardian (15 April 2014) UN special rapporteur criticises Britain's 'in-your-face' sexist culture

[9] ONS (August 2013) Annual mid-year population estimates, 2011 and 2012

Submission

21. The petitioners provided a written submission in advance of their appearance at the Committee. The petitioners argued that Page 3 is an objectification of women which a majority of people do not support. The petitioners draw a link between the way that women are portrayed in the media and gender stereotyping, negative attitudes towards women, and acts of domestic and sexual violence. The petition questioned whether stocking the Scottish Sun is compatible with the Scottish Parliament's Equalities Framework, and suggested that an equality impact assessment be undertaken.

Action

22. The Committee is invited to agree what action it wishes to take in respect of the petition. Options include—

    (1) To seek written views. For example, the Committee may wish to seek views on the petition from:

    - The Scottish Sun
    - The Presiding Officer
    - The Equality and Human Rights Commission

    (2) To take any other action that the Committee considers appropriate.

Public Petitions Committee

12th Meeting, 2014 (Session 4), Tuesday 17 June 2014

PE1518 on Meaningful Public Consultation within the Scottish Planning System

Note by the Clerk

PE1518 – Lodged 1 May 2014
Petition by George M Chalmers calling on the Scottish Parliament to urge the Scottish Government to clearly define, for the sake of good order within the planning system, the criterion which allows developers to ignore or avoid the Town and Country Planning (Hierarchy of Developments) (Scotland) Regulations 2009, with particular regard to Major Development applications.
Link to petition webpage

Purpose

1. This is a new petition that the Committee is invited to consider and agree what action it wishes to take. The Committee has invited the petitioner to speak to the petition.

Background – the following information is taken from the SPICe briefing

2. All proposed developments fall within one of the three categories of the hierarchy of developments, which can be described as follows:

   i. National developments: Developments designated as of national significance in the National Planning Framework for Scotland
   ii. Major developments: Nine classes of large scale development are defined as major developments in The Town and Country Planning (Hierarchy of Developments) (Scotland) Regulations 2009
   iii. Local Developments: Any development which is not a national or major development is automatically categorised as a local development.

3. Where an application sits within the hierarchy influences how it is handled. For example, national and major developments are subject to a statutory requirement for pre-application consultation by the prospective developer.

What is "a development"?

4. Development is defined as "the carrying out of building, engineering, mining or other operations in, on, over or under land, or the making of any material change in the use of any buildings or other land, or the operation of a marine fish farm in the circumstances specified in section 26AA" in Section 26(1) of the Town and Country Planning (Scotland) Act 1997 ("the 1997 Act").

5. However, the 1997 Act, the Town and Country Planning (Hierarchy of Developments) (Scotland) Regulations 2009 and the associated Circular 5/2009:

Hierarchy of Developments do not define what constitutes "a development". The Regulations and Circular use the terms "development" and "application", which describe development proposals that form the subject of a specific planning application.

6. Circular 5/2009 is clear that "There is no scope for local interpretation of what constitutes a major development or local development either by planning authorities, by applicants or by other stakeholders in the planning system." This specifically prevents planning authorities from considering multiple applications for local developments on adjacent sites, which taken together would constitute a major development, as a major development.

Scottish Government Action

7. The Scottish Government has not considered this issue.

Scottish Parliament Action

8. The Scottish Parliament has not considered this issue.

Action

9. The Committee is invited to agree what action it wishes to take in respect of the petition. Options include—

(1) To seek written views. For example, the Committee may wish to ask:

Scottish Government—
Heads of Planning Scotland—
Royal Town Planning Institute Scotland—

- What are your views on what the petition seeks?

(2) To take any other action that the Committee considers appropriate.

Public Petitions Committee

12th Meeting, 2014 (Session 4), Tuesday 17 June 2014

PE1519 on saving Scotland's seals

Note by the Clerk

PE1519 – Lodged 6 May 2014
Petition by John F Robins, on behalf of Save Our Seals Fund, calling on the Scottish Parliament to urge the Scottish Government to stop issuing licences permitting salmon farming, salmon netting and salmon angling interests to shoot and kill seals in Scottish waters and instead require that salmon farmers either move their farms into on-shore tank systems or legally require marine salmon farmers to install and maintain the high-strength, high tension predator exclusion nets they require to meet their legal obligation under the Animal Health & Welfare (Scotland) Act 2006 to protect their stock from the attention of predators. We further ask that the Scottish Parliament ask the Scottish Government to legislate to close down all salmon netting stations in Scottish waters thus allowing tens of thousands of Atlantic Salmon and seatrout to return to their native rivers to breed.

Link to petition webpage

Purpose

1. This is a new petition that the Committee is invited to consider and agree what action it wishes to take. The Committee has invited the petitioner to speak to the petition.

Background – the following information is taken from the SPICe briefing

2. Two seal species, the grey seal *Halichoerus grypus* and harbour or common seal *Phoca vitulina*, are present around the coast of Scotland in internationally important numbers.

3. Both grey and harbour seals are listed in Annex II of the EU Habitats Directive (92/42/EEC), requiring specific areas to be designated for their protection. 34 Special Areas of Conservation (SAC) have been designated for grey seals, 14 of which are in Scotland, and 23 for harbour seals, 16 of which are in Scotland.[1]

4. Approximately 38% of the world's grey seals breed in the UK and 88% of these breed at colonies in Scotland with the main concentrations in the Outer Hebrides and in Orkney. There are also breeding colonies in Shetland, on the north and east coasts of mainland Britain and in SW England and Wales.

5. Approximately 30% of European harbour seals are found in the UK. Harbour seals are widespread around the west coast of Scotland and throughout the

[1] Using JNCC SAC search facility by species:
http://jncc.defra.gov.uk/protectedsites/SACselection/SAC_searchpage.asp

Hebrides and Northern Isles. On the east coast, their distribution is more restricted with concentrations in the major estuaries of the Thames, The Wash, Firth of Tay and the Moray Firth. Scotland holds approximately 79% of the UK harbour seal population, with 16% in England and 5% in Northern Ireland.[2]

6. Under the Conservation of Seals Act 1970 and the Marine (Scotland) Act 2010, the Natural Environment Research Council (NERC) has a duty to provide scientific advice to government on matters related to the management of seal populations. NERC has appointed a Special Committee on Seals (SCOS) to formulate this advice. This advice is published annually.

7. The most recent advice was published in 2013. The advice estimates a total UK population in 2012 of 112,300 grey seals and 37,300 harbour seals.

8. The advice includes information on population trends in grey and harbour seals. Although the number of grey seal pups throughout Britain has grown steadily since the 1960s when records began, the advice is that there is clear evidence that the population growth is levelling off in all areas except the central and southern North Sea where growth rates remain high. The numbers born in the Hebrides have remained approximately constant since 1992 and growth has been levelling off in Orkney since the late 1990s.

9. The advice explains that harbour seal counts were stable or increasing until around 2000 when declines were seen in Shetland (which has declined by 30% since 2000), Orkney (down 75% since 2000) and the Firth of Tay (down 85% since 2000). However, other regions are now stable following a period of decline (the Moray Firth) and some have been largely continually stable (west coast of Highland region and the Outer Hebrides). Research into the causes of the decline in harbour seals is continuing. This is currently focussed on the potential for competition with grey seals through investigations into dietary and foraging area overlap; investigations into the impact of disease, particularly the ingestion of toxins from harmful algae and physical trauma[3] as a major cause of mortality in some regions.

10. The Conservation of Seals Act 1970 prohibits taking seals during a close season (01/09 to 31/12 for grey seals and 01/06 to 31/08 for harbour seals) except under licence. The Act also allows for specific Conservation Orders to extend the close season to protect vulnerable populations. After consultation with NERC, three such orders were established providing year round protection to grey and harbour seals on the east coast of England and in the Moray Firth and to harbour seals in the Outer Hebrides, Shetland, Orkney and the east coast of Scotland between Stonehaven and Dunbar (effectively protecting all the main concentrations of harbour seals along the east coasts of Scotland and England).

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[2] The SCOS 2013 report states that there are no established haul-out sites in Wales

[3] The SCOS 2013 report states: “research into the causes of the recently identified unusual mortalities (“corkscrew” seal deaths) is continuing. The hypothetical link between these traumatic deaths and ducted propellers is being tested using scale models in industrial test facilities. The hypothesis that seals are acoustically attracted to certain propellers is also being tested in the SMRU captive seal facility and in the wild through behavioural sound playback studies.”

Scottish Parliament Action

11. Parliament passed the Bill which has been enacted as the Marine (Scotland) Act 2010 on 4 February 2010. Part 6 of the Act prohibits the taking of seals except under licence. Licences can be granted for the protection of fisheries, for scientific and welfare reasons and for the protection of aquaculture activities. In addition, the Act allows Scottish Ministers to designate haul-out sites[4] where it is an offence to recklessly or intentionally harass seals. The Marine (Scotland) Act 2010 maintains the abovementioned seal conservation areas in Scotland. Section 129 of the Act requires Scottish Ministers to review and report on the operation of the seal licensing regime by January 2016, and every five years subsequently.

12. Parliament passed the Bill which has been enacted as the Aquaculture and Fisheries (Scotland) Act 2013 on the 15 May 2013. Section 3 of the Act allows Scottish Ministers, through subordinate legislation, to set technical standards for the equipment used in fish farming, and requires fish farmers to train their staff in the proper use of that equipment. The main motivation of the provision is to improve the standard of equipment used to prevent escapes of farmed fish, which can impact on wild fish. As part of its work on the Bill at Stage 1, the Rural Affairs, Climate Change and Environment Committee took evidence about the problem of seal predation of farmed fish, and the use of "seal scarers" at fish farms.[5] In its Stage 1 report the Committee concluded:

> 123. The Committee acknowledges the threat seal attacks pose to both the commercial performance of fish farms, and to the wider marine environment in terms of the impact on the number of escapes. However, the Committee notes concerns raised about the number of seals which are being shot at fish farms as part of predator control.
>
> 124. The Committee welcomes the efforts being made in some parts of the aquaculture industry to pursue alternative measures, in terms of netting and other equipment, which would prevent seals being able to break through into farm cages.
>
> 125. The Committee acknowledges that audio seal scarers may be a cost effective option to keep seals away from fish farms. However, it believes it is essential that such devices are as humane as possible. The Committee therefore recommends the Scottish Government works with the aquaculture industry to ascertain how effective and widespread the use of such devices is, in order to establish clear guidelines on their use.
>
> 126. The Committee welcomes the work being done by the University of St Andrews [Sea Mammal Research Unit] to develop an audio device which is as humane as possible for seals and does not harm other species and is encouraged that the device has secured investment, and a technology

[4] Sites where seals come out of the water e.g. to rest, sleep, breed
[5] See pages 21-23 of the Committee's Stage 1 report, available here: http://www.scottish.parliament.uk/S4_RuralAffairsClimateChangeandEnvironmentCommittee/Reports/rur-13-01w.pdf

licence, which may see it established in the market place as a viable solution for the aquaculture industry. The Committee recommends the Scottish Government continues to work with the University of St Andrews to encourage further investment in, and development of, the device.

Scottish Government Action

13. In October 2002 a Scottish Seals Forum was established to bring together stakeholders with an interest in seal issues. The Forum provides an opportunity to exchange information relevant to the conservation and management of Scottish seal populations and is supported by a Working Group which carries forward the work of the Forum between meetings.

14. Marine Scotland are the licensing authority for seals under the Marine (Scotland) Act 2010 and licences are issued annually authorising the killing or taking of seals for a number of activities including research, to protect the health and welfare of farmed fish and to prevent serious damage to fisheries or fish farms. Before granting a seal licence Marine Scotland must have regard to any information they have about damage which seals have already done to the fishery or fish farm concerned and the effectiveness of non-lethal alternative methods of preventing seal damage to the fishery or fish farm concerned.

15. Licences can include the method of killing or taking the seals, the maximum number of seals that can be killed or taken and details on the steps which must be taken in order to reduce the risk of unnecessary suffering if a seal is injured while attempting to kill or take it. A seal licence that authorises killing should specify the type of firearm which must be used, the weather conditions in which a person may attempt to shoot a seal, the distance the person should be away from the animal while shooting and prohibit shooting from an unstable platform. It can also include information on the recovery of the carcass and may include other conditions such as areas where shooting can take place, species of seal that can be taken or killed, the circumstances in which seals may be taken or killed and any period when they may not be taken or killed.

16. Licence applications are assessed against Potential Biological Removal (PBR) for each of the seven Management Regions (East coast, Moray Firth, Shetland, Orkney and the North coast, Outer Hebrides, West Highland, South-West Scotland) which have been defined by the Sea Mammal Research Unit (SMRU) to include a metapopulation of seals. PBR is the number of individual seals that can be removed from the population without causing a decline in the population and is calculated annually by SMRU using the latest seal counts.

17. The annual report of the Special Committee on Seals includes responses to questions from Defra, Marine Scotland and Natural Resources Wales. Marine Scotland develops the questions it poses working with the Scottish Seals Forum. These questions and a link to the advice received, are posted on the Scottish Government website.

18. The 2013 advice includes responses to the following questions, posed by Marine Scotland:

Q. What is the current state of knowledge of interactions between seals and salmon netting stations and possible mitigation measures? And what new research might be usefully done in this area?

A. Studies suggest that specialist seals are responsible for the majority of seal activity and presumably predation events at netting stations. Acoustic deterrent devices (ADDs) are effective in reducing seal activity and predation. In a recent study during periods when the ADD was switched on, significantly fewer seals were observed and significantly more fish were landed per hour than when the ADD was switched off

Q. What is the current state of knowledge of interactions between seals and fin fish farms and possible mitigation measures?

A. Current studies have found that there does not seem to be any relationship between damage levels at different salmon farm locations and the proximity or local density of seals. ADDs are also used to deter seals from these sites but there are concerns about their effect on cetaceans and the need to ensure they operate reliably. Increased or improved application of standard husbandry techniques, notably cage structure and net tensioning, can substantially reduce the incidence of seal damage to farmed salmon.

Q. What, if any, changes are suggested in the Permitted/Potential Biological Removals (PBRs) for use in relation to the seal licence system?

A. No changes are suggested to the Permitted/Potential Biological Removals method used in relation to the seal licence system.[6]

19. The Scottish Government held a consultation in 2011 on proposals to designate seal haul out sites under the Marine (Scotland) Act 2010. The Scottish Government has worked with other organisations to produce the Moray Firth Seal Management Plan, which is the first strategic attempt to address the whole issue of the impact of seal predation on salmon fisheries in a co-ordinated way. It seeks to answer many outstanding questions, in particular, the extent to which seals affect salmonid[7] fisheries and whether this can be effectively addressed through focused seal management.

20. In relation to the Aquaculture and Fisheries (Scotland) Act 2010 powers to set technical standards in relation to fish farming equipment, a Containment Working Group was established under the auspices of the Ministerial Group for Sustainable Aquaculture (MGSA) in 2013 – building on the work of the Improved Containment Working Group. The group's agreed deliverables include:

    - To deliver a Scottish Technical Standard for fish farm equipment and associated guidance by 2015.

[6] The responses quoted are the emboldened summary of the response included in the report. Additional information is provided by the Special Committee on Seals in each response.
[7] Salmonids include salmon and sea trout, a migratory form of brown trout

- Inform draft regulations in relation to Scottish technical requirements enabling provision in the Aquaculture and Fisheries (Scotland) 2013 Act by 2015.

Action

21. The Committee is invited to agree what action it wishes to take in respect of the petition. Options include—

    (1) To seek written views. For example, the Committee may wish to seek views on the petition from:

    - The Scottish Government
    - Marine Scotland
    - The Special Committee on Seals

    (2) Given how recently the Aquaculture and Fisheries Act (Scotland) Act 2013 was considered and passed, the Committee may wish to refer this petition to the Rural Affairs Climate Change and Environment Committee to consider as an extension of its work on that Bill.

    (3) To take any other action that the Committee considers appropriate.

Public Petitions Committee

12th Meeting, 2014 (Session 4), Tuesday 17 June 2014

PE1520 on unrestricted freedom to build on plots of up to 1 acre

Note by the Clerk

PE1520 – Lodged 14 May 2014
Petition by Mary Laing calling on the Scottish Parliament to urge the Scottish Government to allow every owner-occupier of a plot of up to 1 acre in area the unrestricted freedom to build or extend accommodation for themselves or family members, without any requirement that they seek planning permission, a building warrant, or other authorisation.

Link to petition webpage

Purpose

1. This is a new petition that the Committee is invited to consider and agree what action it wishes to take.

Background – the following information is taken from the SPICe briefing

2. The Scottish planning system operates under the provisions of the Town and Country Planning (Scotland) Act 1997 ("the 1997 Act"), as amended, and the Planning (Listed Building and Conservation Area) (Scotland) Act 1997, as amended, plus associated regulations, circulars and guidance.

3. The requirement to obtain planning permission for the development of land is a fundamental principle of the Scottish planning system. Development is defined in Section 26 of the 1997 Act as "the carrying out of building, engineering, mining or other operations in, on, over or under land, or the making of any material change in the use of any buildings or other land, or the operation of a marine fish farm in the circumstances specified in Section 26AA".

4. The requirement to obtain planning permission for every development would quickly overwhelm the planning system. To prevent this from happening certain smaller developments, as set out in the Town and Country Planning (General Permitted Development) (Scotland) Order 1992, are automatically deemed to have planning permission. These are often referred to as "permitted developments". If a proposed development does not meet the criteria for a permitted development then a developer must obtain planning permission from the relevant planning authority prior to starting work. More information on the permitted development rights available to householders can be found in Scottish Government Planning Circular 1/2012: Guidance on Householder Permitted Development Rights.

Scottish Government Action

5. The Scottish Government has recently completed a major revision to the operation of the Scottish planning system through the implementation of the Planning etc. (Scotland) Act 2006, the creation and review of the Scottish Planning Policy and development of the third National Planning Framework. The Scottish Government also undertook a review of householder permitted development rights in 2011, which resulted in new householder permitted development rights coming into operation on 6 February 2012.

Scottish Parliament Action

6. The Scottish Parliament has not considered the proposals suggested in the petition.

7. Since the petition was lodged, the clerks have been unable to make contact with the petitioner despite several attempts. Emails have been sent and a letter was returned unopened marked “addressee unknown”.

Action

8. The Committee is invited to agree what action it wishes to take in respect of the petition. It is suggested that as there has been no contact from the petitioner since the end of March the petition be closed.

Public Petitions Committee

12th Meeting, 2014 (Session 4), Tuesday 17 June 2014

PE1408 on Updating of Pernicious Anaemia/Vitamin B12 Deficiency Understanding and Treatment

Note by the Clerk

PE1408 – Lodged 12 October 2011
Petition by Mrs Andrea MacArthur calling on the Scottish Parliament to urge the Scottish Government to review and overhaul the current out-dated and ineffective method of diagnosing and treating pernicious anaemia/vitamin B12 deficiency.
Link to petition webpage

Purpose

1. The Committee last considered this petition on 12 November 2013 and agreed to write to the British Committee for Standards in Haematology (BCSH) and defer further consideration until the BCSH guidelines had been published. The guidelines have been published and the Committee is invited to agree what action it wishes to take on the petition.

Background

2. Diagnosis of vitamin B12 deficiency or pernicious anaemia is usually made using a blood test. Folate levels will also be checked as this is another common vitamin B deficiency causing similar symptoms.

3. An alternative test made available at one lab in England is the Active-B12 test. Whereas standard tests measure the total amount of B12 in the blood, the Active-B12 test measures the amount of B12 present in a 'bio-available' form.

4. In response to Parliamentary Question S4W-01761 on guidelines for GPs on using the Active-B12 test, the then Cabinet Secretary for Health, Wellbeing and Cities Strategy, Nicola Sturgeon MSP, responded:

> *"No guidelines have been given to GPs on using the Active-B12 test for diagnosing and treating pernicious anaemia as this is not the generally used way of diagnosing this condition in NHS Scotland."*

Committee Consideration

5. The Committee first considered this petition on 15 November 2011, following which it held a Chamber debate on 7 March 2012. It was noted that the BCSH expected to publish guidelines on the diagnosis of B12 and folate deficiency. Following publication, the Minister undertook to ask Healthcare Improvement Scotland to look at what more could be done to aid understanding. The Minister also confirmed that he would bring the debate to SIGN's attention to enable it to reflect on the views expressed.

6. The petition was considered further by the Committee on 20 March 2013, 12 June 2012, 18 September 2012, 11 December 2012 and 3 September 2013.

7. The BCSH contacted the Committee in May enclosing its '*Guidelines for the diagnosis and treatment of Cobalamin and Folate disorders*' and advising that the guidelines would be published "in the next few weeks" in the British Journal of Haematology.

8. Since publication, the Scottish Government has written to the Committee to confirm that it is "currently considering" them. The Scottish Government has alerted the Scottish Haematology Society to the guidelines' publication, requesting that it brings them to the attention of their members.

Action

9. The Committee is invited to consider what action it wishes to take in respect of this petition. Options include—

(1) To ask the Scottish Government to clarify exactly what action it is taking following the publication of the BCSH guidelines and to what timescale.

(2) To take any other action that the Committee considers appropriate.

Public Petitions Committee

12th Meeting, 2014 (Session 4), Tuesday 17 June 2014

PE1480 on Alzheimer's and dementia awareness

Note by the Clerk

PE1480 – Lodged 22 June 2013
Petition by Amanda Kopel, on behalf of the Frank Kopel Alzheimer's Awareness Campaign, calling on the Scottish Parliament to urge the Scottish Government to raise awareness of the daily issues suffered by people with Alzheimer's and dementia and to ensure that free personal care is made available for all sufferers of this illness regardless of age.
Link to petition webpage

Purpose

1. This petition was last considered by the Committee on 1 April 2014. At that meeting the Committee agreed to defer consideration of the petition until after the Cabinet Secretary for Health and Wellbeing had made a statement to Parliament on residential and continuing care. The Cabinet Secretary made a statement on 8 May 2014 and the Committee is invited to agree what action it now wishes to take on the petition.

Background

2. The Committee will be aware that Frank Kopel passed away on 16 April 2014.

3. The petition raises two main issues for consideration. The first relates to raising awareness of the issues faced by those with Alzheimer's and dementia. The second is a call for free personal care to be extended to all those with dementia regardless of age.

Alzheimer's disease and dementia in Scotland

4. In its latest statistical release[1] for 2014, Alzheimer Scotland estimates that approximately 88,000 people have dementia in Scotland, of which 3,200 are under the age of 65. Other publications[2] by Alzheimer's Scotland note that whilst there are many different illnesses that cause dementia, Alzheimer's disease is the most common. It estimates that 55% of those who have dementia will have Alzheimer's disease.

Free personal care

5. Free Personal and Nursing Care (FPNC) was introduced on 1 July 2002 through the Community Care and Health (Scotland) Act 2002 (the 2002 Act) and

[1] Alzheimer Scotland (2014) Statistics: Number of people with dementia in Scotland 2014. This statistical release also provides estimate by local authority area in Scotland.
[2] For example, Alzheimer Scotland (2003) Alzheimer's disease. [Last updated October 2012].

associated regulations, and is available for everyone aged 65 and over who have been assessed by the local authority as needing it.

Scottish Government Action

Raising awareness of Alzheimer's disease and dementia

6. The Scottish Government made dementia a national priority in 2007. It set a national target on improving diagnosis rates in 2008 and published an initial 3-year National Dementia Strategy in 2010. Following a period of engagement with stakeholders that began in 2012, the Scottish Government developed a second strategy[3], published in 2013, which sought to build upon the first.

Free Personal Care for those aged under 65

7. The most significant review of the FPNC policy that has been undertaken since the inception of the policy was that by Lord Sutherland, who reported[4] in April 2008. It made no recommendations to extend the policy to other care groups.

Cabinet Secretary's Statement to Parliament

8. The Cabinet Secretary for Health and Wellbeing made a statement to Parliament on Care and Caring on 8 May 2014. This statement followed the publication of the report by the Independent Review of NHS Continuing Healthcare on 2 May 2014.

9. The review, which was tasked with looking at the provision of continuing care, recommended that the "principles and recommendations [of the report] should apply equally to individuals of all ages". In his statement, the Cabinet Secretary said—

> "Having worked constructively with the task force's members, we will also engage with those key stakeholders to look at personal care services that are provided to people under 65 who have complex needs and to examine whether those people are receiving effective support."[5]

Committee consideration

10. The Committee considered this petition for the first time on 17 September 2013, heard evidence from the petitioner and agreed to seek views from the Scottish Government and Alzheimer Scotland.

11. In its submission of 19 November 2013, the Scottish Government stated that it had no plans to lower the eligibility criteria for Free Personal and Nursing Care. The current 3-year National Dementia Strategy was considering how to improve care pathways for those with early onset dementia and, as part of implementing the strategy, more would be done to identify what further actions are required in key areas.

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[3] Scottish Government (2013) Scotland's National Dementia Strategy 2013-16
[4] Lord Sutherland (2008) Independent Review of Free Personal Care in Scotland.
[5] The Scottish Parliament (2014) *The Official Report, 8 May 2014 (*Col 30748)

12. Alzheimer Scotland supports the aims of the petitioner to increase awareness of dementia. However in its view, extending free personal care to those with dementia under age 65 could discriminate against people with other conditions and many would still be charged for services. Alzheimer Scotland supports the national dementia strategy but the petition highlights the "substantial work" that remains to be done.

13. COSLA advised that local authorities provide non-residential care services within different local circumstances that result in differences in cost. It is currently working with a wide range of stakeholders, including Alzheimer Scotland, on delivering a review of the charging guidance to achieve greater consistency and less variation in charges.

Action

14. The Scottish Government has indicated that it will look into the provision of personal care for under-65s with complex needs; the Committee may wish to ask for more details on the scope and timescale for this work.

Public Petitions Committee

12th Meeting, 2014 (Session 4), Tuesday 17 June 2014

PE1492 on Co-location of GP Practices and Community Pharmacies

Note by the Clerk

PE1492 – Lodged 1 November 2013
Petition by Alan Kennedy calling on the Scottish Parliament to urge the Scottish Government to:

- Ensure that, within the scope of the NHS (Pharmaceutical Services) (Scotland) Regulations 2009 as amended by SSI/2011/32, co-located community pharmacies and GP practices are permitted and encouraged where patients affected by recent pharmacy applications have expressed the wish to have this facility and suitable space exists to allow this service to operate;
- Review the impact of new pharmacy applications, particularly in rural areas, to establish whether guidance to NHS boards or further amendments to the legislation are necessary.

Link to petition webpage

Purpose

1. The Committee last considered this petition on 6 May 2014 and agreed to defer consideration until the report on the Scottish Government's 'Consultation on the Control of Entry Arrangements and Dispensing GP Practices' had been published and the amendment regulations laid. The report was published and regulations laid on 30 May 2014. The Committee is invited to agree what action it wishes to take in respect of the petition.

Background

2. Over the last decade there have been a number of controversial cases involving community pharmacy applications in areas served by dispensing practices. This is because once a community pharmacy application is approved, it is likely that an NHS board will cease to contract with a practice to provide dispensing services. As a result, some applications have faced opposition from both the public and dispensing doctors, who claim that they undermine the sustainability of rural practices and do not reflect patient preference for a dispensing practice.

3. During this time, a number of concerns arose in relation to the processes around pharmacy applications and, as a result, the Scottish Government reviewed and amended the regulations in 2009 and in 2011.

4. In addition, in September 2013, the Cabinet Secretary for Health and Wellbeing announced a review of the regulatory framework that supports the community pharmacy applications process (PQ S4W-16801). This followed the publication of the 'Review of NHS Pharmaceutical Care of Patients in the Community in Scotland' (Aug 2013) by Dr Hamish Wilson and Prof Nick Barber. The Scottish Government responded the following month with the publication of 'Prescription

for Excellence: A vision and action plan for the right pharmaceutical care through integrated partnerships and innovation'.

5. In November, the Health and Sport Committee asked the Cabinet Secretary a question, submitted by the petitioner as part of 'Ask the Health Secretary', on the co-location of GP practices and pharmacies. The Cabinet Secretary responded:

> "I intend to…put in place, sooner rather than later, a system that takes much more account of what the community needs and wants, instead of allowing large monopolies to dominate proceedings. That is exactly what we are looking at, and I will bring forward proposals to the Parliament on that." (Official Report, 12th November 2013, Col 4568)

Committee Consideration

6. Just prior to the Committee considering the petition for the first time on 10 December 2013, the Scottish Government announced its consultation on the Control of Entry Arrangements and Dispensing GP Practices. This ran from 12 December 2013 to 20 February 2014.

7. The Committee considered the petition again on 4 March 2014 and wrote to the Scottish Government and the Convener of the Health and Sport Committee. In his response, the Cabinet Secretary for Health and Wellbeing outlined his intention to lodge amendment regulations following an independent analysis of the responses to the Scottish Government's consultation and the publication of the report.

8. At its meeting on 6 May 2014 the Committee agreed to defer consideration until the report on the Scottish Government's consultation had been published and amendment regulations had been laid. These documents have now been published: news release; report on its Consultation on the Control of Entry Arrangements and Dispensing GP Practices; and amendment regulations.

9. The amendment regulations come into force on 28 June 2014 and are subject to negative procedure. The lead committee for consideration is the Health and Sport Committee, which must report on the regulations by 11 August 2014.

10. The petitioner has written to the Committee. Although he welcomes the laying of the amendment regulations, he reiterates some of his concerns. These are primarily in relation to encouraging joint location of GP and pharmacy, where such a move has local support, and the redress that is available to communities that have been affected by this issue.

Action

11. As the Health and Sport Committee is the lead Committee for the regulations, it is suggested that the petition be referred to that Committee for it to take such action as it considers appropriate.

Public Petitions Committee

12th Meeting, 2014 (Session 4), Tuesday 17 June 2014

PE1505 on Awareness of Strep B in Pregnancy and Infants

Note by the Clerk

PE1505 – Lodged 18 February 2014
Petition by Jackie Watt calling on the Scottish Parliament to urge the Scottish Government to introduce new guidelines advising that all expectant mothers are given information about Strep B and are either screened for Strep B as a matter of routine or given information on where to go if they wish to be tested privately.
Link to petition webpage

Purpose

1. The Committee considered this petition for the first time on 18 March 2014 and agreed to write to the Scottish Government, the UK National Screening Committee and the American College of Obstetricians and Gynaecologists. Responses have been received and the Committee is invited to consider what action it wishes to take in relation to the petition.

Background

2. Group B Streptococcus (GBS) is a bacterium that is naturally present in the bodies of about one quarter of the UK population (National Screening Committee (NCS), 2012). It usually inhabits the digestive system and/or the female reproductive tract and is normally completely harmless. GBS is present in the vagina of about 21% of pregnant women in the UK and can be transferred to newborn infants at the time of delivery (Group B Strep Support, 2013). The majority of women who carry GBS give birth to healthy babies, but occasionally a newborn's immune system can be overcome and the bacteria can cause infection, illness and death.

3. Out of 700,000 babies born each year across the UK, approximately 350-400 of these will develop GBS[1] (an incidence of 0.5–0.57 per 1,000 births) (NSC, 2012). The incidence of GBS in Scotland in 2012 is estimated to be slightly lower (0.47 per 1,000 births[2]). Thus, although GBS is considered rare, it is recognised by the Royal College of Obstetricians and Gynaecologists (RCOG) as the leading cause of life-threatening infections in newborn infants (RCOG, 2012).

4. The UK currently operates a risk-factor based strategy to combat neonatal GBS disease. Risk factors are incidences that are known to increase the likelihood of early-onset GBS disease.

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[1] The subject of the petition, and thus also this briefing, is concerned primarily with 'early-onset GBS', defined as a GBS infection that occurs within the first 7 days of life, as the incidence of late-onset GBS is not impacted by maternal screening procedures.
[2] Figures produced by Health Protection Scotland (HPS) as part of Ministerial response to Parliamentary Question S4W-1805.

5. The UK National Screening Committee (UKNSC) is a part of Public Health England, an executive agency of the Department of Health. Its role is to advise Ministers and the NHS in the four UK countries regarding all aspects of screening, including reviewing evidence for implementing new population level screening programmes. The UKNSC recently reviewed the current guideline and decided against the introduction of routine screening for GBS.

6. There are currently two versions of the GBS test, referred to as the direct plating method or Enriched Culture Medium (ECM) method. The ECM test is considered the 'gold standard' and is considerably more sensitive than direct plating.

7. The ECM test is currently not widely available at NHS hospitals but may be purchased privately by post for a fee (including laboratory processing) of approximately £35 (GBSS, 2012).

Scottish Government Action

8. In response to Parliamentary Question S4W-15631 on the issue of testing, the Minister for Public Health stated on 26 June 2013 that:

> "The Scottish Government is given independent advice by the UK National Screening Committee (NSC), the independent expert advisory group who advise ministers and the NHS in the four UK countries about all aspects of screening.
>
> The NSC reviewed the policy for Group B Streptococcus (GBS) in November 2012. This review considered all the available medical evidence regarding the risks and benefits of screening all pregnant women. The Committee recommended that a national screening programme for Group B Streptococcus should not be introduced. The NSC will continue to keep screening for GBS under review and will consider the policy again in 2015-16, or earlier, if significant new evidence emerges.
>
> The Royal College of Obstetricians and Gynaecologists (RCOG) issued revised guidelines, 'The Prevention of Early-onset Neonatal Group B Streptococcal Disease', in June 2012. This recommends an approach to antibiotics administration based on maternal risk factors. NHS boards in Scotland are expected to follow professional guidance issued by the RCOG to identify which women, based on maternal risk factors, should be screened for GBS during pregnancy."

Committee Consideration

9. The Committee considered this petition on 18 March 2014 and heard evidence from the petitioner and the Chief Executive of Group B Strep Support. The Committee agreed to write to the Scottish Government, the UK National Screening Committee (UKNSC) and the American College of Obstetricians and Gynaecologists (ACOG).

10. The Scottish Government responded advising that its policy is guided by independent advice from the UKNSC, and this does not recommend routine screening for GBS. The Scottish Government will remind NHS Boards of the importance of raising awareness of GBS. It will also work with Health Scotland to revise the *Ready Steady Baby!* leaflet to include information on GBS.

11. The UKNSC sets out its position and why it does not recommend routine screening. There will be a review in Spring 2015 of the evidence on GBS screening and all interested stakeholders are invited to contribute to the review's consultation. A number of areas of further study and research that are planned or underway are also outlined.

12. In response to the Committee's request for the evidence that had been gathered on the benefits and harms resulting from routine screening for GBS, the ACOG provided a number of links to online resources on GBS and women's health more generally. Of specific relevance to the petition, is the ACOG Committee on Obstetric Practice's opinion paper on *Prevention of Early-Onset Group B Streptococcal Disease in Newborns*.

13. A follow-up request was made to the ACOG for specific comment on the petition but, to date, no response has been received.

14. The petitioner has provided further evidence, reiterating her call for routine screening for GBS and the provision of information for all pregnant women.

Action

15. The Committee is invited to agree what action it wishes to take in respect of the petition. Options include—

    1) To write to the Scottish Government and NHS Health Scotland to request that the petitioner and other stakeholders are consulted as part of the revision of the *Ready Steady Baby!* leaflet to include information on GBS;
    2) To defer consideration of the petition to a future meeting to await the UKNSC review of the evidence on GBS screening.

Public Petitions Committee

12th Meeting, 2014 (Session 4), Tuesday 17 June 2014

PE1503 on a review of A9 speed camera proposals

Note by the Clerk

PE1503 – Lodged 21 December 2013
Petition by Mike Burns, on behalf of Average Speed Cameras on the A9 are not the answer, The A9 Safety Group recently proposed an Average Speed Camera System on the A9 in order to reduce fatalities. This group believes this is the incorrect decision based on official statistics which show that breaking the speed limit accounts for only 2% of accidents on the A9, whereas overtaking manoeuvres account for nearly 50% of A9 accidents. We believe that the A9 Safety Group has not investigated adequate alternatives to deal with the majority cause of A9 accidents and the modelling used to propose the A9 system is flawed. We believe there should be a full parliamentary debate on the proposal along with the reformation of the A9 Safety Group to allow representation from car drivers, who make up over 95% of A9 road users, yet have not been involved in A9 Safety Group meetings. We believe as the evidence is flawed and does not have full parliamentary support, the A9 Speed Camera System must be delayed indefinitely until an investigation is carried out to look at the workings of the A9 Safety Group, Transport Scotland and investigate other proposals which would have a direct impact on overtaking, which is the main official cause of accidents on the A9.
Link to petition webpage

Purpose

1. The Committee last considered this petition on 22 April 2014 and agreed to write to the petitioner and the A9 Safety Group to urge them to meet to discuss the issues raised in the petition.

Background

2. Keith Brown MSP, Minister for Transport and Veterans, announced the installation of an average speed camera system on the A9 trunk road between Dunblane and Inverness on 26 July 2013.

3. The operating companies responsible for day-to-day management and maintenance of the A9 carried out an evidence-based review on accidents, vehicle speeds, traffic flows and existing speed statistics for the A9 Safety Group. With regards speed issues it was found that 37% of cars and 95% of HGVs were exceeding the posted speed limit at traffic counters located on single carriageway sections of the route between Perth and Inverness.

4. The installation of average speed cameras was the key outcome of the Interim Safety Plan developed by the A9 Safety Group. Other measures in the Interim Plan include a forthcoming education campaign on safe overtaking, increased enforcement and ongoing maintenance. The Group is also looking into visibility

at junctions, signing and lighting, additional Variable Message Signs and conducting ongoing research into accidents on the route.

5. The Scottish Government is committed to the dualling of the A9 between Perth and Inverness by 2025. Transport Scotland announced on 5 December 2013 that a pilot increase of the HGV speed limit on single carriageway sections of trunk road from 40mph to 50 mph would begin on the A9, coinciding with the introduction of average speed cameras.

Committee Consideration

6. Following initial consideration of this petition at its meeting on 28 January 2014, the Committee agreed to write to the Scottish Government/Transport Scotland, members of the A9 safety group, the AA, the RAC and the Institute of Advanced Motorists. The Committee received a number of responses.

7. In its response of 25 February 2014, Transport Scotland explained the role of the A9 Safety Group and set out a case for the introduction of an Average Speed Camera System (ASCS) on the A9. It also outlined the other initiatives and measures that have been taken to improve road safety on the A9. Further details, including a timetable for the initial works, were provided in Transport Scotland's follow-up letter of 27 March 2014.

8. Although not unanimous, the majority of the members of the A9 Safety Group that submitted evidence support the introduction of an ASCS on the A9, or agree that its introduction will have a positive impact on road safety. Several of the member organisations believe there is compelling evidence that demonstrates that an ASCS will reduce the number of road traffic accidents and the severity of injuries in those accidents that do occur. Some of the members also highlight that an ASCS will only enforce the current legal speed limit on the A9 and question why this would be objected to.

9. The Federation of Small Businesses (FSB) and the Scottish Council for Development and Industry (SCDI) do not share the view that an ASCS is an appropriate measure for improving road safety on the A9. Both organisations refer to the detrimental economic impact that may result from such measures. However, the SCDI does state that "average speed cameras may be part of the solution on some limited sections of the road".

10. At the meeting on 28 January 2014, the Committee noted concerns raised in relation to a perceived lack of representation on the A9 Safety Group from motorists and regular A9 road users. This was the basis for the Committee's decision to write to the AA, the RAC and the Institute of Advanced Motorists (IAM) to seek their views on the issues raised by the petition.

11. Shortly after that meeting, the IAM accepted an invitation to join the A9 Safety Group. In its response to the Committee, the IAM highlights the initial concerns it had over the installation of an ASCS covering the whole length of the A9. However, it states that the new proposal to create seven discrete enforcement zones only on single carriageway sections of the road is "a much better design

solution." The IAM's response also states that there is "no scientifically proven evidence…that ASC systems distract drivers", and questions why, on road safety grounds, anyone "can object to a system that merely enforces the existing legal speed limit." In its response, the AA concludes that "average speed cameras are a necessary but integral part of improving safety along the A9."

12. The Committee considered the petition on 22 April 2014 and agreed to write to the petitioner and the A9 Safety Group to urge them to meet to discuss the issues raised in the petition.

13. The chair of the A9 Safety Group, Stewart Leggett, wrote to Mr Burns on 9 May 2014, offering to meet with him. Mr Leggett suggested a number of dates for the meeting and offered to meet in either Glasgow or Perth. Mr Burns turned down the offer of the meeting and asked that the whole of the A9 Safety Group hold a public meeting in Inverness.

14. A further letter from Mr Leggett to Mr Burns dated 9 June reiterated the offer to meet and outlined some of the engagement work the A9 Safety Group has undertaken, including public information exhibitions in Inverness.

Action

15. The Committee is invited to consider what action it wishes to take in respect of the petition. It is suggested that as the majority of responses received by the Committee were of the view that average speed cameras would have a positive impact on road safety and as work has now begun on installing the equipment that the petition is closed.