

# Health, Social Care and Sport Committee

## 22nd Meeting, 2022 (Session 6), Tuesday, 14 June 2022

### Subordinate legislation

### Note by the clerk

#### Purpose

1. This paper invites the Committee to consider the following negative instruments:
  - [Novel Foods \(Authorisations\) and Smoke Flavourings \(Modification of Authorisations\) \(Scotland\) Regulations 2022](#)
  - [National Health Service \(Optical Charges and Payments and General Ophthalmic Services\) \(Scotland\) Amendment Regulations 2022](#)
  - [The National Health Service \(Vocational Training for Dentists\) \(Miscellaneous Amendment\) \(Scotland\) Regulations 2022](#)

#### Procedure for negative instruments

2. Negative instruments are instruments that are “subject to annulment” by resolution of the Parliament for a period of 40 days after they are laid. This means they become law unless they are annulled by the Parliament. All negative instruments are considered by the Delegated Powers and Law Reform Committee (on various technical grounds) and by the relevant lead committee (on policy grounds).
3. Under Rule 10.4, any member (whether or not a member of the lead committee) may, within the 40-day period, lodge a motion for consideration by the lead committee recommending annulment of the instrument.
4. If the motion is agreed to by the lead committee, the Parliamentary Bureau must then lodge a motion to annul the instrument to be considered by the Parliament as a whole. If that motion is also agreed to, the Scottish Ministers must revoke the instrument.
5. If the Parliament resolves to annul an SSI then what has been done under authority of the instrument remains valid but it can have no further legal effect. Following a resolution to annul an SSI the Scottish Ministers (or other responsible authority) must revoke the SSI (make another SSI which removes the original SSI from the statute book.) Ministers are not prevented from making another instrument in the

same terms and seeking to persuade the Parliament that the second instrument should not be annulled.

6. Each negative instrument appears on the Health, Social Care and Sport Committee's agenda at the first opportunity after the Delegated Powers and Law Reform Committee has reported on it. This means that, if questions are asked or concerns raised, consideration of the instrument can usually be continued to a later meeting to allow the Committee to gather more information or to invite a Minister to give evidence on the instrument. Members should however note that, for scheduling reasons, it is not *always* possible to continue an instrument to the following week. For this reason, if any Member has significant concerns about a negative instrument, they are encouraged to make this known to the clerks in advance of the meeting.
7. In many cases, the Committee may be content simply to note the instrument and agree to make no recommendations on it.

## Guidance on subordinate legislation

8. Further guidance on subordinate legislation is available on the Delegated Powers and Law Reform Committee's web page at:  
<http://www.scottish.parliament.uk/parliamentarybusiness/CurrentCommittees/delegated-powers-committee.aspx>

## Recommendation

9. The Committee is invited to consider any issues which it wishes to raise in relation to these instruments.

### **Clerks to the Committee**

**9 June 2022**

**SSI 2022/168**

**Title of Instrument:** Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Scotland) Regulations 2022

**Type of Instrument:** Negative

**Laid Date:** 20 May 2022

**Meeting Date:** 14 June 2022

**Minister to attend meeting:** No

**Motion for annulment lodged:** No

**Drawn to the Parliament's attention by the Delegated Powers and Law Reform Committee?** No.

10. The Delegated Powers and Law Reform Committee considered the instrument at its meeting on [7 June 2022](#) and made no recommendations in relation to this instrument.

**Reporting deadline:** 28 June 2022

**Purpose**

11. The purpose of the instrument is to implement the decision made by the Minister for Public Health, Women's Health & Sport in relation to five novel foods, authorising four new novel foods for placement on the market in Scotland and one extension of use for an already authorised novel food. The instrument also authorises the transfer of authorisation holder for five smoke flavourings.

12. The policy notes states that this SSI aligns Scotland with England and Wales and similar EU legislation for these novel food products, all of which have now been authorised by the EU Commission. It further states that this SSI will also align Scotland with England and Wales regarding the transfer of authorisation holder for smoke flavourings. While only one transfer is currently being progressed in the EU, the businesses concerned have been informed that they should submit applications for transfer with the EU separately.

13. A copy of the Scottish Government's Policy Note is included in **Annexe A**.

**SSI 2022/169**

**Title of Instrument:** National Health Service (Optical Charges and Payments and General Ophthalmic Services) (Scotland) Amendment Regulations 2022

**Type of Instrument:** Negative

**Laid Date:** 20 May 2022

**Meeting Date:** 14 June 2022

**Minister to attend meeting:** No

**Motion for annulment lodged:** No

**Drawn to the Parliament's attention by the Delegated Powers and Law Reform Committee?** No.

14. The Delegated Powers and Law Reform Committee considered the instrument at its meeting on [7 June 2022](#) and made no recommendations in relation to this instrument.

**Reporting deadline:** 27 June 2022

**Purpose**

15. The purpose of this instrument is to increase NHS optical voucher values by 2%, to support more patients with eye problems being safely managed within the community, to enable remote consultations and to deliver other miscellaneous changes.

16. A copy of the Scottish Government's Policy Note is included in **Annexe B**.

**SSI 2022/170**

**Title of Instrument:** The National Health Service (Vocational Training for Dentists) (Miscellaneous Amendment) (Scotland) Regulations 2022

**Type of Instrument:** Negative

**Laid Date:** 20 May 2022

**Meeting Date:** 14 June 2022

**Minister to attend meeting:** No

**Motion for annulment lodged:** No

**Drawn to the Parliament's attention by the Delegated Powers and Law Reform Committee?** No.

17. The Delegated Powers and Law Reform Committee considered the instrument at its meeting on [7 June 2022](#) and made no recommendations in relation to this instrument.

**Reporting deadline:** 28 June 2022

#### **Purpose**

18. These Regulations make amendments to The National Health Service (Vocational Training for General Dental Practice) (Scotland) Regulations 2004 to (a) change the employer of dentists undertaking Vocational Training from training practices to NHS Education for Scotland (NES) and (b) continue an exemption from vocational training for dentists holding certain European diplomas.
19. A copy of the Scottish Government's Policy Note is included in **Annexe C**. The Equality Impact Assessment is available [here](#).

**POLICY NOTE****THE NOVEL FOODS (AUTHORISATIONS) AND SMOKE FLAVOURINGS (MODIFICATION OF AUTHORISATIONS) (SCOTLAND) REGULATIONS 2022****SSI 2022/168**

The above instrument was made by the Scottish Ministers in exercise of the powers conferred by Articles 12(1) and 32A(3) of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, amending Regulation (EU) No. 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No. 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No. 1852/2001, Article 11(4) of Regulation (EC) No. 2065/2003 of the European Parliament and of the Council on smoke flavourings used or intended for use in or on foods, and all other powers enabling them to do so. The instrument is subject to negative procedure.

**Summary Box**

The purpose of the instrument is to implement the decision made by the Minister for Public Health, Women's Health & Sport in relation to five novel foods, authorising four new novel foods for placement on the market in Scotland and one extension of use for an already authorised novel food. The instrument also authorises the transfer of authorisation holder for five smoke flavourings.

**Policy Objectives**

These Regulations are required to give legislative effect to the Minister's decision with respect to authorisation of four new novel foods for placement on the market in Scotland, one extension of use for an already authorised novel food and the transfer of authorisation holder for five smoke flavourings. The Regulations will add the new novel foods to the list of authorised novel foods set out in Regulation (EU) 2017/2470 and will update the entry in that list for the novel food for which there is an authorised extension of use. They will also update the list of authorised smoke flavourings set out in Regulation (EU) 1321/2013 with the details of the new authorisation holders.

At the end of the Implementation Period the UK inherited the EU Commission's legal obligation to process applications for the authorisation of regulated food products. Assessing food safety in Scotland is the responsibility of Food Standards Scotland (FSS) as the 'food safety authority'.

The authorisation of these novel foods and smoke flavouring transfers of authorisation holder rests with the Scottish Ministers. The retained law obligates the Scottish Ministers to prescribe authorisation of the relevant novel foods and the modification of smoke flavouring authorisations, including the transfer of authorisation holders, in law. This SSI comprises the authorisations by the Scottish Ministers of applications made to them either for a new novel food authorisation or extension of use of a currently authorised novel food, or the transfer of authorisation holder for a currently authorised smoke flavouring. This instrument will apply to Scotland only.

This SSI aligns Scotland with England and Wales and similar EU legislation for these novel food products, all of which have now been authorised by the EU Commission.

This SSI will also align Scotland with England and Wales regarding the transfer of authorisation holder for smoke flavourings. While only one transfer is currently being progressed in the EU, the businesses concerned have been informed that they should submit applications for transfer with the EU separately. All relevant information on the authorisation of the novel food products will be entered in the list of authorised novel foods in Regulation (EU) 2017/2470 and all relevant information on the smoke flavouring transfers of authorisation holder will be entered into the list of authorised smoke flavourings in Regulation (EU) 1321/2013.

Further information in relation to the lists of authorised novel foods and smoke flavourings can be obtained from Food Standards Scotland, Pilgrim House, Old Ford Road, Aberdeen, AB 11 5RL.

## **Consultation**

In compliance with the requirements of Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, there has been open and transparent public consultation during the preparation and evaluation of this SSI. There were two consultations, the first ran from 17 December 2021 until 11 February 2022 and the second from 31 March 2022 until 13 April 2022.

There were no responses to the first consultation and there were four to the second. Of the four responses to the second consultation, three were regarding the smoke flavouring transfers and one was regarding the novel foods. All responses were supportive, with one concern raised that the smoke flavouring transfers need to come into force before 30 June 2022, which this instrument enables them to do. This concern was addressed and responded to. Summaries of the consultation responses and replies to these were published on the consultation pages on Citizen Space for both the [first](#) and [second](#) consultations. A list of those who replied to the consultation and who agreed to publication of their details and response was included in these summaries published on Citizen Space.

## **Impact Assessments**

FSS consider that a specific BRIA (Business and Regulatory Impact Assessment) is not required for these novel food authorisations or smoke flavouring transfers. The costs to businesses are contained in Regulation (EU) 2015/2283 on novel foods, which requires authorisation for novel foods to be placed on the market or for extensions of use of current authorisations. Similarly, the costs to businesses are contained in retained Regulation (EC) No. 2065/2003 on smoke flavourings which requires authorisation for modifications of smoke flavourings, including transfers of authorisation holder. This SSI gives legislative effect to the Minister's decisions and does not introduce any new costs to businesses or industry. The new novel food authorisations will likely result in the reallocation of wealth from existing to new product lines. No other impact assessments are required.

## **Financial Effects**

The Minister for Public Health, Women's Health & Sport confirms that a BRIA is not necessary as the instrument has no financial effects on the Scottish Government, local government or on business.

Food Standards Scotland  
18 May 2022

**POLICY NOTE****THE NATIONAL HEALTH SERVICE (OPTICAL CHARGES AND PAYMENTS AND GENERAL OPHTHALMIC SERVICES) (SCOTLAND) AMENDMENT REGULATIONS 2022****SSI 2022/169**

The above instrument was made in exercise of the powers conferred by sections 26, 28A(4), 70(1), 73(a), 74(a) and 105(7) and paragraphs 2(2) and 2A of schedule 11 of the National Health Service (Scotland) Act 1978. The instrument is subject to negative procedure.

**Purpose of the instrument: To increase NHS optical voucher values by 2%, to support more patients with eye problems being safely managed within the community, to enable remote consultations and to deliver other miscellaneous changes.**

**Policy objectives**

The instrument amends the National Health Service (Optical Charges and Payments) (Scotland) Regulations 1998 (“the 1998 Regulations”) and the National Health Service (General Ophthalmic Services) (Scotland) Regulations 2006 (“the 2006 Regulations”).

In addition to minor amendments, this instrument makes the changes detailed below.

**Optical vouchers - Uprating of values**

Optical vouchers provide financial help towards the purchase of new, or repair or replacement of existing, glasses or contact lenses for certain categories of people, including children under 16, those aged 16 to 19 in qualifying full-time education and those who require complex lenses. For adults, other than assistance for complex appliances, help is income related, with those in receipt of certain benefits automatically entitled to a voucher while others on low incomes may be entitled to help under the NHS Low Income Scheme.

This instrument amends the 1998 Regulations by increasing the values of all optical voucher categories and supplements by 2%, ensuring that the values of optical vouchers issued in Scotland continue to match those issued elsewhere in the UK.

**Optical vouchers - Special facial characteristics supplement**

If a patient is under the care of the hospital eye service and, for clinical reasons, requires a more expensive, specially-made frame for their glasses (because a basic spectacle frame will not fit correctly), then a special facial characteristics supplement can be added to the value of an optical voucher issued by the relevant NHS Board. A typical example in these circumstances would be a patient who has Down’s Syndrome.

The 1998 Regulations does not currently permit this supplement to be included on an optical voucher issued by an optometrist or ophthalmic medical practitioner (“OMP”) based in the community.

This instrument makes things more convenient for patients and aims to reduce pressure on the hospital eye service by amending the 1998 Regulations to permit an optometrist or OMP based in the community to issue an optical voucher which includes the special facial characteristics supplement.

### **Referrals following a General Ophthalmic Services eye examination**

In the early stages of the COVID-19 pandemic, routine face-to-face eye care services were suspended and a network of Emergency Eyecare Treatment Centres (“EETCs”) was established across Scotland where patients with emergency and potentially serious sight-threatening eye conditions could be referred to for treatment after being remotely triaged<sup>1</sup>.

Most of the EETCs were based in the community and resourced with an Independent Prescriber (“IP”) optometrist, who are additionally qualified and who can be issued with a NHS prescribing pad that enables them to issue NHS prescriptions to patients. This emergency referral system was highly successful in ensuring that most patients with emergency eye problems were managed safely in the community and did not need to be seen in hospital.

The General Optical Council (Rules relating to Injury or Disease of the Eye) Order of Council 1999 (“1999 Rules”), SI 1999/32672, as amended, permits an optometrist to refer a patient suffering from a suspected injury or disease of the eye to another optometrist who has the appropriate qualifications or expertise, which might be an IP optometrist. However, under the 2006 Regulations, following a General Ophthalmic Services (“GOS”) eye examination an optometrist or OMP can only currently refer such a patient to their General Practitioner or to the hospital eye service.

Building on the proven success of the emergency referral and treatment system used in the early stages of the COVID-19 pandemic, and noting the 1999 Rules, this instrument amends the 2006 Regulations by enabling an optometrist or OMP to refer a patient with a serious eye problem to an IP optometrist or other OMP following a GOS eye examination. This will support more NHS patients with eye problems being managed in the community closer to their home, helping to reduce the burden on hospitals and General Practitioners.

### **GOS eye examinations undertaken remotely**

Prior to the COVID-19 pandemic, and in accordance with the 2006 Regulations, GOS eye examinations were undertaken in person between the patient and the optometrist or OMP.

To help ensure the continued safe management of patients during the COVID-19 pandemic, the Scottish Government had allowed for optometrists and OMPs submitting GOS payment claims to NHS National Services Scotland (“NSS”) for remote consultations provided to patients when deemed clinically appropriate and safe<sup>3</sup>.

Although GOS activity in most areas of Scotland has now largely recovered to pre-pandemic levels, and this is predominantly being undertaken in person, there is general agreement in the community eye care sector and NHS Scotland that the ability to manage a patient remotely (where deemed clinically appropriate and safe, and under certain rules and circumstances) should form a permanent part of GOS in Scotland in order to support safe and accessible care.

With NHS Scotland no longer on an emergency footing as of 30 April 2022, the Scottish Government considers this to be an appropriate time to deliver this change. This instrument accordingly amends the 2006 Regulations to provide the flexibility for GOS to be undertaken using remote facilities.

In addition to the relevant amendments to the 2006 Regulations, a new Statement of remuneration (which is made and published by Scottish Ministers under regulation 17 of the 2006 Regulations) will be issued in due course providing additional detail on the circumstances in which an optometrist or OMP can submit a payment claim to NSS for a GOS eye examination which is undertaken using remote facilities.

## **Mandatory training for GOS practitioners**

### **Introduction of “cut-off” date**

The 2006 Regulations provides that all optometrists and OMPs (except bodies corporate) included on a NHS Board’s Ophthalmic List must, as part of their Terms of Service for providing GOS, undertake training provided by NHS Education for Scotland (“NES”) in each “relevant period” (paragraph 3A of Schedule 1 of the 2006 Regulations). On 1 January 2021, each relevant period changed to a 12 month period spanning a calendar year.

An optometrist or OMP who is not already included on any NHS Board’s Ophthalmic List in Scotland must, at the point they are included on any such List, currently undertake and satisfactorily complete the mandatory training for the relevant period, irrespective of which date in the calendar year they are added to the List.

When an optometrist or OMP is added to an Ophthalmic List towards the end of the calendar year, this creates challenges for NES in delivering and assessing the mandatory training and for NHS Boards in monitoring and enforcing compliance with the mandatory training requirement.

As such, it is considered that an optometrist or OMP who is added to a NHS Board’s Ophthalmic List after 31 October in any calendar year, and who is otherwise not already included on another NHS Board’s Ophthalmic List, should not have to satisfactorily complete the mandatory training for that relevant period. This instrument delivers this policy by accordingly amending the 2006 Regulations.

### **Removal of requirement to send certificate of satisfactory completion to NHS Board**

After an optometrist or OMP has satisfactorily completed the mandatory training for the relevant period, they must currently send a certificate confirming this fact to each NHS Board on whose Ophthalmic List they are included. The original policy intention for this was to assist NHS Boards in monitoring and enforcing compliance with the mandatory training requirement.

In practice, this has proven to be administratively burdensome for optometrists and OMPs and NHS Boards, and it is considered that the requirement to provide such certificates should cease. This instrument delivers this policy by accordingly amending the 2006 Regulations.

An alternative, more efficient means of assisting NHS Boards in monitoring and enforcing compliance with the mandatory training requirement is being developed.

## **Renaming ‘continuing education and training’ as ‘continuing professional development’**

The General Optical Council (the regulatory body for the optical sector in the UK) consulted in 2021 on UK-wide changes to its continuing education and training scheme, including changing its description to “continuing professional development”<sup>4</sup> and subsequently secondary legislation made this change<sup>5</sup>.

Taking into account this UK-wide change, and in order to align with the same term used across other professions, this instrument amends the 2006 Regulations by replacing the term continuing education and training with continuing professional development. In addition to this amendment, a new Statement of remuneration made and published by Scottish Ministers under regulation 17 of the 2006 Regulations will be issued in due course reflecting this terminology change.

### **Consultation**

Optometry Scotland and NHS Boards have been consulted in the preparation of this instrument. These views have been factored into the preparation of this instrument.

### **Impact Assessments**

There are no Equalities, Children's Rights and Wellbeing, Island Communities, Socio-economic or Strategic Environmental impact issues arising from this instrument.

### **Financial Effects**

The Minister for Public Health, Women’s Health and Sport confirms that no Business and Regulatory Impact Assessment is necessary as the instrument itself has no financial effects on business and the third sector. The financial effect on the Scottish Government from the increase in optical voucher values will be met from within existing budgets.

### **Scottish Government Directorate of Primary Care Dentistry and Optometry Division May 2022**

1 [https://www.sehd.scot.nhs.uk/pca/PCA\(O\)\(2020\)06.pdf](https://www.sehd.scot.nhs.uk/pca/PCA(O)(2020)06.pdf)

2 <https://www.legislation.gov.uk/uksi/1999/3267/contents/made>

3 [https://www.sehd.scot.nhs.uk/pca/PCA2020\(O\)05.pdf](https://www.sehd.scot.nhs.uk/pca/PCA2020(O)05.pdf)

4 <https://consultation.optical.org/standards-and-cet/cetreview/>

5 <https://www.legislation.gov.uk/uksi/2021/1234/contents/made>

**POLICY NOTE****THE NATIONAL HEALTH SERVICE (VOCATIONAL TRAINING FOR DENTISTS) (MISCELLANEOUS AMENDMENT) (SCOTLAND) REGULATIONS 2022****SSI 2022/170**

The above instrument was made in exercise of the powers conferred by sections 2(5), 25(1) and (2), and 105(7) of the National Health Service (Scotland) Act 1978. The instrument is subject to negative procedure.

**Purpose**

These Regulations make amendments to The National Health Service (Vocational Training for General Dental Practice) (Scotland) Regulations 2004 to (a) change the employer of dentists undertaking Vocational Training from training practices to NHS Education for Scotland (NES) and (b) continue an exemption from vocational training for dentists holding certain European diplomas.

**Policy Objectives**

Currently dentists in vocational training are recruited and paid by NES and yet are employed by training practices (or in a very small minority in private dental services clinics where the employer is a Health Board). The amendments would mean that the employer of dental vocational trainees changes to NES.

Moving to a single point of contact for all vocational trainees on employment issues should allow for a more standardised and efficient HR service for trainees and for other stakeholders for managing vocational trainees employment queries and issues. Consistent application of NES employment policies to all vocational trainees ensures a fair and equitable approach can be applied where there are any employment issues. Closer NES involvement in supporting trainees with employment issues may also allow for earlier recognition and resolution of any problems.

NES already have tested policies, systems and processes in place which can be adopted and aligned to the needs of vocational trainees, this includes supporting more complex areas that can arise during the vocational training year including for example sickness absence, maternity leave, paternity leave and conduct issues.

Further benefits would be clarification of employment responsibilities and mitigation of risk whilst maximising digital solutions.

We are also taking the opportunity to broadly mirror changes made in other countries of the UK by exempting those dentists who hold a relevant European diploma from being required to do vocational training in Scotland. A relevant European diploma is defined in the Dentists Act 1984 (see section 15 and 53) as an appropriate European diploma or a qualification granted in a relevant European State, with a “relevant European State” meaning an EEA State or Switzerland. We are largely reinstating the position that was in place before Brexit, ensuring dentistry in Scotland continues to benefit from those dentists with this qualification joining the workforce.

## **Consultation**

In relation to the change of employer, NES conducted a consultation with relevant groups in late 2018/early 2019, and communications were produced July 2019, which were circulated to interested parties. The consultation exercise indicated that stakeholders agreed that the change in employer to NES would be a positive change.

## **Impact Assessments**

In relation to the change of employer, an EQIA was undertaken which will be published on the gov.scot website.

## **Financial Effects**

No Business and Regulatory Impact Assessment (BRIA) is necessary as the instrument has no financial effects on the Scottish Government, local government or on business.

## **Scottish Government Health Workforce**

**May 2022**