EXPLANATORY MEMORANDUM TO

THE MEDICAL ACT 1983 (AMENDMENT) (KNOWLEDGE OF ENGLISH) ORDER 2014

2014 No. [XXXX]

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 This order makes amendments to the Medical Act 1983 to:

- Give the General Medical Council (GMC) the power to refuse a licence to practise in circumstances where the medical practitioner is unable to demonstrate the necessary knowledge of English; and

- Create a new fitness to practise category of impairment, relating to having the necessary knowledge of English.

2.2 These amendments have been subject to a 12 week public consultation and are supported by the GMC.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Context

4.1 An Inquiry by the House of Commons Health Committee; the Committee's Report, 'The Use of Overseas Doctors in Providing Out of Hours Services (5th report session 2009-10)[1]' was published on 8th April 2010, which recommended that the Government make the necessary changes to legislation that would allow the GMC to language test applicants applying for registration (see paragraph 23).

This report followed the death of David Gray in 2008 after he received medical treatment by Dr Ubani, a German national, working his first shift as an out of hours doctor for a GP Service Provider. Dr Ubani gave Mr Gray an overdose of diamorphine (10 times the recommended maximum dose) resulting in Mr Gray's death.

Following a change of administration, the Coalition Government responded to this issue stating in the 2010 Coalition Agreement, "We will seek to stop foreign healthcare professionals working in the NHS unless they have passed robust language and competence tests". In its response to the Health Committee's

[1] http://www.publications.parliament.uk/pa/cm200910/cmselect/cmhealth/441/441.pdf

Report[2], the Government committed to jointly explore options with the GMC for developing a strengthened system of language controls, and supported the recommendation for doctors to be able to communicate effectively (see paragraph 6).

Following the European Commission's Green Paper on proposals to amend the Mutual Recognition of Professional Qualifications Directive 2005/35/EC[3], the House of Lords EU Committee published a report in response to those proposals which addressed the issue of language testing of EEA doctors (see paragraphs 72-91)[4]. The Government's response to the Lords Report stated that it needed further clarification from the Commission as to what level of checks were permitted and at which point during the process they could be undertaken (pages 12 to 15).

The issue of language testing of EEA doctors was raised again during the GMC's annual accountability hearing before the Health Committee (see paragraphs 53-57 of the Report). The Committee reaffirmed that they were looking to "the Government, the GMC and the relevant EU institutions to produce a long-term solution to this problem within a timescale which reflects the potential risks to patients". Subsequently, the Government presented its response in the form of a Command Paper to Parliament in February 2013[5] confirming its intention to strengthen the arrangements to ensure that all doctors have sufficient knowledge of English before being able to work in the UK by amending the Medical Act to enable (i) language checking to be linked to the licence to practise and (ii) to include language deficiency as an "impairment" for the purposes of the fitness to practise provisions under the Act (see pages 3-5).

The draft Order is seeking to amend Part I (Registration); Part IIIA (Licence to Practise and Revalidation); and Part V and Schedule 4A (Fitness to Practise) of the Medical Act to give effect to these intentions.

The amendments will enable the GMC to implement the changes through their rule making powers granted under the Act. Section 29A of the Act places a duty on the GMC to make regulations with regard to licences to practise; and Schedule 4 of the Act enables the GMC to make rules about fitness to practise procedures. The necessary amendments to those regulations are, of course, subject to the approval of this Order, however, a concurrent consultation was undertaken to facilitate the implementation of the proposals as soon as possible. Those rules will be subject to approval by the Privy Council.

5. Territorial Extent and Application

5.1 This instrument applies to all of the United Kingdom.

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[2] Response to the House of Commons Health Committee Report: The use of overseas doctors in providing out–of–hours services: Fifth Report of Session 2009–10.

[3] Brussels 22.06.22 COM(2011) 367 final.

[4] House of Lords European Union Committee / 22nd Report of Session 2010-12: Safety First: Mobility of Healthcare Professionals in the EU (19.11.2011).

[5] http://www.official-documents.gov.uk/document/cm85/8520/8520.asp

6. European Convention on Human Rights

The Parliamentary Under Secretary of State for Health, Dr Daniel Poulter has made the following statement regarding Human Rights:

In my view the provisions of the Medical Act 1983 (Amendment) (Knowledge of English) Order 2014 are compatible with the Convention rights.

7. Policy background

What is being done and why?

7.1 The policy objectives

The draft order seeks to amend the Medical Act to strengthen the system of language controls that can be applied to medical practitioners wishing to practise in the UK.

International medical graduates seeking registration with the GMC must demonstrate that they have the necessary knowledge of English, before they can be registered with the GMC.

However, if a European doctor[6] applies to register and practise medicine in the UK (there are around 5000 applications from European doctors to register with the GMC each year), the GMC are not able to require evidence of their English language capability as a condition of their registration.

This is due to the application of European law, in particular the Mutual Recognition of Professional Qualifications Directive, which prohibits the language checking of professionals as a condition of recognition. However, the Directive requires that a person who benefits from recognition shall have the necessary language skills for practising the profession in the host Member State[7]. This requirement has been clarified under the recent revision to the Directive, which now specifically states that language controls may be imposed if the profession to be practised has patient safety implications, provided that they are carried out after recognition of the qualification and are necessary and proportionate.

The proposed changes are in response to concerns that some doctors working in the UK do not hold the necessary English language skills to practise in a safe and competent manner and, as such, are putting patients' lives at risk. These concerns were triggered by the death of Mr David Gray in 2008, who died after receiving an overdose of diamorphine administered by Dr Ubani, a

[6] In this document, the term 'European doctor' refers to a doctor who is:

- A national of a relevant European state (this means a national of a member state of the European Economic Area or Switzerland), or
- Not a national of a relevant European state, but is entitled to be treated no less favourably for these purposes because he or she benefits under the Citizenship Directive from an enforceable community right.

[7] See Article 53 of Directive 2005/36/EC.

German national. The issue has subsequently been raised during a Parliamentary Inquiry and in various Scrutiny Committee Reports (see paragraph 4 for further details). In response to these reports, the Government has worked closely with the GMC to develop proposals in order to ensure patient safety and reduce the risk posed by insufficient language proficiency of European doctors, without contravening European law.

The Department of Health and the GMC have developed a solution which means that doctors from European countries will still have their medical qualification recognised by the GMC, whilst enabling the GMC to assure themselves that the doctors who hold a licence to practise have the necessary knowledge of English to be able to practice safely, and has concluded with the following proposals:

(i) To place an explicit statutory duty on Responsible Officers to ensure English language competence as part of the recruitment process at a local level; and

(ii) To make amendments to the Medical Act 1983 to strengthen the GMC's powers around language controls at a national level, through the licence to practise and fitness to practise processes.

With regard to the first proposal, this was delivered on 1st April 2013, through the Medical Profession (Responsible Officers) (Amendment) Regulations 2013. The role of the Responsible Officer was established under The Medical Profession (Responsible Officers) Regulations 2010[8], whose role it is to evaluate the fitness to practise of doctors with whom they have a connection. There was an initial duty on responsible officers to ensure that medical practitioners had the qualifications and experience appropriate to the work to be performed[9]. However, in response to concerns over this issue, the above regulations were amended so that the responsible officer is now also required to "ensure that medical practitioners have sufficient knowledge of English language necessary for the work to be performed in a safe and competent manner''. However, as a consequence of the devolution settlements, this requirement applies to England only.

With regard to the second proposal above, the draft order is seeking to implement these changes by amending the Medical Act for the following purposes:

(i) To give the GMC the power to require applicants to provide evidence of English language capability as part of the licensing process where concerns about language have been identified during the registration process; this will enable the GMC to apply language controls on applicants following registration, with the ability to refuse a licence to practise in circumstances where a medical practitioner cannot demonstrate that they have the necessary knowledge of English to practise is a safe and competent manner;

[8] S.I. 2010/2841.

[9] See regulation 16(2)(a).

(ii) To create a new category of impairment relating to the necessary knowledge of English, strengthening the GMC's ability to take fitness to practise action where concerns about the language competence of any doctor are identified.

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Licence to practise

The effect of the Order is that the GMC will be able to refuse a licence to practise if the applicant is unable to demonstrate the necessary level of English. However, to ensure transparency and consistency of approach, the Government's proposals require the GMC to publish statutory guidance relating to the evidence, information or documents to be provided by a medical practitioner for the purposes of demonstrating that the practitioner has the necessary knowledge of English. The licensing authority will be required to have regard to that guidance when determining whether a doctor has demonstrated the necessary knowledge of English.

Fitness to practise

The effect of the Order will be to strengthen the GMC's powers to investigate English language knowledge as an impairment for the purposes of the fitness to practise procedures under the Act. Section 35C of the Act sets out the provisions of the Investigation Committee to investigate an allegation made to the GMC, in respect of a doctor's fitness to practise. Subsection (2) prescribes the circumstances which may trigger an investigation into a doctor's fitness to practise, and the draft Order is seeking to insert 'not having the necessary knowledge of English' under subsection (2) to enable it to be investigated as a fitness to practise issue.

Paragraph 5A of Schedule 4 (professional performance assessment) gives the GMC power to make rules authorising the giving of directions by any of the Investigation Committee, Fitness to Practice Panel or such other person as specified in the rules, requiring an assessment of the standard of a registered person's professional performance to be carried out. The intention is that where a doctor is subject to a performance assessment under paragraph 5A, this may include an assessment of the doctor's language knowledge as part of the fitness to practise procedures, which may require the person to undertake a language assessment such as the International English Language Test (IELT). However, it would not be appropriate to assess language under those powers in circumstances where language was the only impairment under investigation. This is because the person would be required to undertake a language assessment, such as the IELT, without the need to appoint an Assessment Team.

The draft Order is therefore seeking to insert a further provision after paragraph 5A of Schedule 4, to make provision for dealing with fitness to practise cases where 'language' is the only ground of impairment. The Order seeks to grant powers to the GMC to make rules authorising the giving of directions for a person to undertake a language assessment.

The Order is seeking powers in the Act for the following provisions:

(i) for the GMC to make rules directing a person to undertake an assessment of their knowledge of English;

(ii) for the rules to include the procedure in respect of such a direction;

(iii) for the Registrar to refer the matter to the Fitness to Practise Panel (FTP) for failure to undertake the assessment or provide information in respect of the assessment;

(iv) for the FTP to make a direction for suspension or conditional registration;

(v) for the practitioner to appeal the decision by the FTP.

7.2 Why legislation is necessary

Licence to practise

The regulation of doctors is governed by the provisions of the Medical Act 1983. The Act makes provision for language controls in respect of overseas doctors (non-EEA) whereby, as a requirement of registration with the GMC, the doctor must show the Registrar that he has the necessary knowledge of English[10]. However, there are no such language requirements in respect of doctors with the relevant UK or EEA medical qualifications. If a doctor holds the required UK or EEA medical qualifications then, subject to the doctor's fitness to practice being impaired, they are entitled to be registered with the GMC as a fully registered practitioner.[11] Once a doctor has been registered with the GMC they are automatically granted a licence to practise[12]. This requirement was inserted into the Act by the Medical Act 1983 (Amendment) Order 2002[13] and came into force on 8th September 2009[14]. This was in preparation for the implementation of the policy relating to the revalidation of doctors. A doctor who holds a licence to practise will now have their fitness to practise reviewed every five years and if they are recommended as still being fit to practise their licence will be revalidated.

The effect of the Act is that where a doctor holds the relevant UK or EEA medical qualification, subject to his fitness to practice being impaired, he is entitled to be registered under the Act as a fully registered practitioner and on first registration is entitled to receive a licence to practise. This is irrespective of whether the doctor has the necessary language skills to perform effectively in a medical setting.

It is therefore necessary to make these changes to the legislation to enable the GMC to withhold a licence to practice if a medical practitioner cannot demonstrate the necessary knowledge of language.

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[10] See section 21B of the Act.

[11] See section 3 of the Act.

[12] See section 29A and 29B of the Act.

[13] SI 2002/3135.

[14] See London, Edinburgh and Belfast Gazettes, 21 August 2009.

Fitness to practise

Section 35C of the Act makes provision for an investigation to be made into a doctor's fitness to practice where it is alleged that his fitness to practise is impaired. The fitness to practise procedures can only be invoked if an allegation is made that the doctor's fitness to practise is impaired by one of the reasons prescribed in section 35C (2). Knowledge of English language is not prescribed as an impairment for these purposes and therefore the fitness to practice procedures cannot be invoked if allegations are made about a doctor's fitness to practise as a result of his insufficient language knowledge. The procedures under section 35C can only be invoked if the doctor's insufficient language skills have resulted in his deficient professional performance[15].

Schedule 4 sets out the powers of the Investigation Committee, Interim Orders Panels and Fitness to Practise Panels. In particular, paragraph 5A of the Schedule enables the Investigation Committee, Fitness to Practise Panel and such other persons as may be specified in the GMC Rules to require an assessment of the doctor's professional performance to be carried out. However, where language deficiency is the only ground of impairment, it would not be appropriate to apply the performance assessment procedures under paragraph 5A and therefore additional provisions are needed.

It is therefore necessary to amend the legislation to enable a fitness to practise panel to require a person to undertake a language assessment as part of the fitness to practise procedures where deficient language is the only ground of impairment.

7.3 The size and nature of the problem it is addressing

There is clear evidence that there is a need to give the GMC additional powers to enable them to carry out proportionate language checks on EEA doctors where concerns are raised following registration but before issuing a licence to practise, to ensure quality of care and patient safety.

The GMC has provided the Department of Health with figures which show that in 2012 there were ten fitness to practise cases concluded by the GMC, which involved concerns about the language skills of doctors from within the European Economic Area (EEA).

In addition, a survey of responsible officers by the England Revalidation Support Team (RST) in 2011, which covered 84,000 doctors (just over half of all doctors) and looked specifically at how concerns about a doctor's practise were dealt with, indicated that, in 2011, there were 66 cases where responsible officers had dealt with linguistic concerns about a doctor. The results of the survey could be said to show there is a need to have some form of language controls at an earlier stage to ensure that those doctors who do not have the necessary knowledge of English are not able to work in the UK.

[15] See section 35C(2)(b) which prescribes deficient professional performance as an impairment for the purposes of the fitness to practise procedures.

The Department believes that the implementation of these proposals will reduce the risk to patient safety where a doctor is subsequently prevented from treating patients due to poor English language capability. For example, on average a GP may see over 5000 patients a year which is 5000 opportunities for harm to be caused due to insufficient language capability. It is the view of the Department that the possible benefits in terms of patient safety cannot be ignored.

In addition, the consultation responses have also highlighted evidence that there is currently the risk of harm by doctors whose English language competence is not good enough. Examples of evidence given in the consultation responses ranged from patients feeling vulnerable and uncomfortable when being treated by doctors who they felt did not have sufficient language skills. To an example given of a consultant not understanding an EU consultant's report due to insufficient language skills. Both are examples which posed a clinical risk to patients.

8. Consultation outcome

8.1 The consultation was made available for comment on Gov.UK and the Department of Health's Citizen Space website over a 12 week period between 7th September 2013 and 2nd December 2013. The Department alerted major stakeholders to the consultation such as the Medical Royal Colleges, the healthcare regulatory bodies and the Devolved Administrations.

The consultation set out the amendments we proposed to make to the Medical Act to give the GMC additional powers in terms of language capability. The consultation questions focused on whether the proposed amendments to the Medical Act are the most effective way of strengthening language controls for doctors in order to improve quality of care and patient safety and whether there are likely to be any impacts or costs which had not already been highlighted in the consultation document.

In total, 54 responses were received, 28 from individuals (mainly identifying themselves as healthcare professionals) and 26 from organisations. Stakeholders who responded include, the British Medical Association, a number of Medical Royal Colleges, the Professional Standards Authority for Health and Social Care, the General Pharmaceutical Council and the General Medical Council.

The vast majority of responses (92.59%) were supportive of the proposals and agreed that strengthening language checks as proposed will improve quality of care and patient safety.

A number of respondents raised questions around what type of evidence of language capability would be required and how the changes would be implemented in a fair and consistent manner. The Department of Health agrees with the need for the new powers to be implemented in a fair and consistent way and that is why the Order specifies that the GMC must publish statutory guidance relating to the evidence, information or documents to be provided by a medical practitioner for the purposes of demonstrating that the practitioner has the necessary knowledge of English. The licensing authority

will be required to have regard to that guidance when determining whether a doctor has demonstrated the necessary knowledge of English.

No elements of the proposed legislation were changed in light of the consultation responses received.

Full details regarding the consultation are available here: https://www.gov.uk/government/consultations/ensuring-doctors-have-sufficient-english-language-capability

9. Guidance

9.1 The draft order imposes a statutory duty on the GMC to publish guidance relating to the evidence to be provided for the purposes of demonstrating that a medical practitioner has the necessary knowledge of English. We therefore do not consider it is necessary for the Department to provide further guidance on this issue.

10. Impact

10.1 The impact on business, charities or voluntary bodies is to individual doctors (who are likely to be EEA applicants) who may be required to take a language test at a cost of around £130 or stopped from working in the UK in some cases where their English language skills are not at the necessary level. The majority of costs will fall to the GMC themselves in terms of set up and administration costs, however the GMC are not classed as a business, charity or voluntary body in terms of their regulatory work.

10.2 The impact on the public sector is nil

10.3 An Impact Assessment has not been prepared for this instrument.

11. Regulating small business

11.1 The legislation does not apply to small business.

12. Monitoring & review

12.1 The policy objective is to ensure that all doctors working in the UK have the necessary knowledge of English to practise in a safe and competent manner. This will be measured by the number of future complaints made to the GMC about concerns of a doctor's language capability. We will ask the GMC to keep the Department updated on this.

13. Contact

Elaine Plumb at the Department of Health Tel: 0113 254 5998 or email: Elaine.plumb@dh.gsi.gov.uk can answer any queries regarding the instrument.