Department of Health

Consultation on the transposition of the revised Mutual Recognition of Professional Qualifications (MRPQ) Directive 2005/36/EC: Amendments to health and care regulators' legislation

Government response

2016

Title: Consultation on the transposition of the revised Mutual Recognition of Professional Qualifications (MRPQ) Directive 2005/36/EC: Amendments to health and care regulators' legislation Government response.
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Contact details: Professional Standards Branch Room 2N09 Quarry House Quarry Hill Leeds LS2 7UE Email: HRDlistening@dh.gsi.gov.uk

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Executive summary

While the people of the UK have voted to leave the European Union (EU), until exit negotiations are concluded, the UK remains a full member of the EU and all the rights and obligations of EU membership remain in force, including the requirements of the Mutual Recognition of Professional Qualifications (MRPQ) Directive (the Directive). During this period the Government will continue to negotiate, implement and apply EU legislation.

Nonetheless, the decision to leave the EU provides the opportunity to make improvements to these arrangements, addressing the concerns of regulators and other parties. Specifically, a number of concerns have been raised about the constraints that MRPQ places on the ability of UK healthcare regulatory bodies carrying out robust checks on both the clinical and language skills of health professionals seeking to practise in the UK. Although the Government values the work of the overseas healthcare professionals currently working in the NHS, it shares these concerns and recognises that a balance needs to be struck between carrying out robust and meaningful checks on overseas staff seeking employment in the UK and the need to ensure that the health and care sectors have proper access to the skilled workers we require. Following the decision to leave the EU, the Government will work with the healthcare regulatory bodies, professional and patient groups across the UK to review the tests that are applied to health professionals seeking to practise in the UK.

Since the consultation, the Department has announced that from September 2018 there will be an increase in medical school places in order to build capacity to train enough medical students to move towards the NHS becoming self-sufficient in training all of the doctors that it needs without an annual reliance on recruiting from overseas.

To ensure that all interested parties had the chance to share their views the Department of Business, Energy and Industrial Strategy (BEIS) consulted on the cross sector changes to the Directive in 2015. The Department of Health subsequently held a six week consultation from 10 December 2015 to 20 January 2016 on the amendments that need to be made to the domestic legislation for health and care professions and on specific changes that only affect a proportion of the health and care professions (doctors, dentists, nurses, midwives and pharmacists) who are classed as the sectoral health professions in relation to the Directive.

We received responses both from individuals and organisations, such as the UK health and care professional regulators, trade unions and professional bodies. All responses have now been considered and subsequently a number of changes have been made to the draft regulations to ensure that they are fit for purpose. The consultation responses have also confirmed our previous considerations that the impact is likely to be low in relation to the potential cost impact of the sectoral specific changes.

The following document provides a snap shot of the consultation responses and conclusions.

We expect to lay the regulations in Parliament to come into force by the end of November. We will continue to work with key stakeholders such as the regulatory bodies to ensure that the changes are implemented appropriately.

Background to consultation

Following the European Commission (EC) review of the Directive, a revised text was formally agreed by the European Parliament in November 2013[1].

The Directive originally came into force in 2007 replacing 15 Directives in the field of recognition of professional qualifications. It provided the first comprehensive modernisation of the EU system since its introduction over 40 years ago. The Directive provides a framework for recognising professional qualifications, with the aim of enabling individuals to work on a permanent or temporary basis across Member States. The Directive includes provisions on:

- knowledge of languages
- minimum standards of training
- temporary service provision
- conditions for recognition
- recognition of professional traineeships
- compensation measures

The key changes in the revised Directive were:

- the introduction of the European Professional Card (EPC) which certain professionals can apply for as proof of recognition of qualification
- a new provision enabling partial access to regulated professions for certain professionals under specific circumstances
- the introduction of an EU-wide alert mechanism managed by the regulators to enhance patient safety across the EU
- the possibility to introduce both common training frameworks and training principles for certain professions

The EC set out a two year transposition period for Member States to transpose amendments to the Directive into domestic law. BEIS subsequently carried out two consultations on the cross sector changes that impact on all professions covered by the Directive including healthcare professions. The consultation documents and responses to these consultations can be found on the Gov.uk website.

BEIS has completed the transposition of the cross sector changes with their regulations coming into force on 18 January 2016. However, a number of further changes need to be made to the domestic legislation for health and care regulators in order to reflect the changes in the Directive.

The Department of Health (the Department) carried out a consultation from 10 December 2015 to 20 January 2016 on the changes relevant to health professions, specifically seeking views on the drafting of the regulations which will amend the UK health and care professions' primary and secondary legislation.

[1] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02005L0036-20140117

The consultation focussed on a number of key areas:

- proposed legislative changes
- content and minimum standards of training
- the EPC
- the alert mechanism
- guidance
- impact on protected characteristics
- monetary impacts

The responses to the consultation have informed the final drafting of the Department's regulations. The responses have also informed our consideration of whether it is necessary to provide health specific guidance on the changes and informed our consideration of any impacts on protected characteristics and any negative monetary impacts.

These points are discussed in more detail in later chapters of this document.

Consultation process

The consultation ran from 10 December 2015 to 20 January 2016 and was taken forward in accordance with the Cabinet Office Consultation Principles. The full text of these principles is on the Gov.uk website[2] .

The consultation[3] was undertaken on behalf of the four UK Health Departments with the agreement of all UK health Ministers.

The consultation was the culmination of more than two years of informal engagement with key stakeholders on the changes to the Directive, the potential impact of the changes on the UK and the most appropriate ways to amend domestic legislation.

The EC set a transposition deadline for all Member States of 18 January 2016. However due to unavoidable delays in the process, the Department has not met this date. The Department continues to work with stakeholders to complete the health specific parts of the transposition as soon as possible.

The Department received 37 consultation responses. A considered decision was made to analyse only 35 responses. This decision was made as one respondent did not provide any information to consider other than their name and selecting that they were a health and care professional, whilst another respondent submitted comments only on a specific part of the Directive not covered by this consultation.

Consultation responses were received from individuals and on behalf of organisations, either via the digital platform 'Citizen Space' or via email.

[2] Department of Health: https://www.gov.uk/government/publications/consultation-principles-guidance.

[3] Department of Health: Department of Health: https://www.gov.uk/government/consultations/mutual-recognition-of-professional-qualifications-in-healthcare

Overview and key themes

The Department analysed 35 responses. Of these, not all respondents answered all of the questions. This could have been because the consultation was wide-ranging in its scope, with some of the changes only impacting on specific healthcare professions. Certain questions were therefore not applicable to all respondents.

The types of respondent can be grouped into the three main categories set out below:

Category	**Number of respondents**	**Percentage (rounded)**
A member of the public	1	3%
Individual working in a health or care profession	9	26%
An organisation	25	71%
Total	**35**	**100%**

In the 'Analysis by Question' chapter of this document, we have provided a snapshot of comments and highlighted key themes where these emerge. A number of responses to questions included comments that did not directly relate to the question being asked. In these instances, where appropriate, we have included these points under the most relevant question.

The main areas where additional comments were received are:

- suggested drafting amendments in relation to the regulations
- the introduction of the EPC
- the alert mechanism
- potential topics to be covered by guidance
- the potential monetary impact

Analysis by Question

Q1. Are there any further legislative amendments, other than those set out in the draft European Qualifications (Health and Social Care Professions) Regulations 2015, which you think are required as a result of the changes to the Directive?

Response	Number of respondents	Percentage (rounded)
Yes	10	29%
No	15	43%
Don't Know	4	11%
Not Answered	6	17%
Total	**35**	**100%**

Of the ten respondents who did think changes were required to the legislation, seven provided additional comments on what these should be. Fifteen respondents felt that no further amendments were required and four replied 'Don't Know'. Six respondents did not answer this question.

Comments made under this question generally came from the regulatory bodies whose governing legislation we are proposing to amend (five out of the seven respondents who proposed amendments to the regulations were regulatory bodies).

A number of respondents suggested that the drafting of the new requirement for professionals wanting to work on a temporary and occasional basis to declare any criminal convictions needed to be considered further to make sure it was fit for purpose. For example, to take into account the possibility that someone might have a spent conviction which would not be relevant.

A number of the regulators made comments in relation to the drafting of the professional traineeship provisions. Some of these were stylistic suggestions in order to more closely reflect the language of the Directive. Some were around clarifying the scope and duration of the professional traineeship that can be taken into account.

One respondent highlighted that the new provisions in the Directive do not apply to Switzerland at this stage as they have not signed an agreement in relation to the revised Directive. We therefore intend to amend the drafting to ensure that the new provisions do not apply to Switzerland.

It was suggested that any future revision of the Directive should have a clear focus on patient safety.

A summary of the changes that we have made, both as a consequence of the responses received as part of this consultation and following further consideration of the Department's draft regulations can be found in the 'Conclusion' chapter of this document.

Q2. Do you think that a pharmacist trainee should take their practical training during their course or at the end of their course?

As set out in the consultation document, the Directive has made changes in relation to the training of pharmacists. In particular Article 44, paragraph 2 of the Directive has been amended to say that a trainee needs to complete a minimum of six months traineeship either 'during or at the end of the theoretical and practical training'.

Previously the EC pharmaceutical advisory committee had advised that the six month period should be towards the end of the training to enable the trainee to put into practice the knowledge and skills they had acquired during their training. The revised Directive now states that this practical period can take place during or at the end of the theoretical and practical training. We therefore wanted to seek views on this change in relation to current UK practices.

Response	**Number of respondents**	**Percentage (rounded)**
During their course	7	20%
At the end of their course	6	17%
Not Answered	22	63%
Total	**35**	**100%**

Due to the specific relevance of this question to the pharmacy profession the majority of respondents (22) did not provide a response to this question. Of the 13 who did respond, seven felt that practical training should be carried out during the course whilst six felt it should be carried out the end of the course.

The Pharmacists' Defence Association (PDA) highlighted a number of issues in relation to the practical traineeship being carried out in the final year of training and summarised that:

> *"…*integrated course (where practical training is completed during the course in the manner set out in the MPC paper) would enhance pharmacy education in the future*."*

Comments from those respondents in support of practical training at the end of the course centred upon the fact that students' knowledge, skills and application are generally at their highest at the end of the five year process. This included Boots UK who stated:

> *"…*we believe that the purpose of the practical training period is to allow trainees to consolidate and contextualise the knowledge they have learnt from their academic studies in to a working practice in a live environment, under the supervision of a qualified pharmacist, and interacting with real patients. This will then allow them to take on the full role of a pharmacist once they are registered. As such, we believe it is important that trainees spend 12 months in practical training immediately prior to registration*"*

Both of the pharmaceutical regulators in the UK (the General Pharmaceutical Council (GPhC) and the Pharmaceutical Society of Northern Ireland (PSNI)) were in favour of the traineeship being conducted at the end of the course. They felt this would make the most of the

opportunities presented by practical training, the value of which may be diminished if taken at an earlier stage during the qualification.

The Royal Pharmaceutical Society (RPS) felt that the training could be undertaken at either stage stating:

> *"…*The RPS believes that such practical training can take place during or at the end of the course as the model of delivery stems from the educational outcome needed – the production of high quality and safe pharmacists is the prime concern*."*

The information collected on this question can be fed into any future consideration of pharmacy training in the UK.

Q3. Do you have any comments on any of the changes in the section above or, where applicable, how these have been inserted into the draft European Qualifications (Health and Social Care Professions) Regulations 2015?

The changes discussed in this section were specific to the sectoral professions. For example, changes in the minimum length of training for doctors, additional requirements in terms of the content of training courses for pharmacists and changes to the entry requirements to the nursing profession.

It must be noted that the standards set out by the Directive are the minimum standards required for the profession, which have been agreed across all Member States. This does not mean that the UK, for example, cannot choose to require additional standards for its own nationals.

Response	**Number of respondents**	**Percentage (rounded)**
Yes	15	43%
No	11	31%
Don't Know	2	6%
Not Answered	7	20%
Total	**35**	**100%**

There was a fairly even split between those who answered with a 'Yes' (15) and those who answered 'No' (11). A significant number did not answer the question at all (seven), with a small number or respondents (two) selecting 'Don't Know'.

Clear themes emerged out of the comments in this section in particular the importance of consistent quality standards across all countries with concerns raised about the efficacy of accepting qualifications from all EU countries without equivalency testing. One health and care professional raised this issue in relation to the dental profession, commenting:

> *"…*It may be difficult to quality control the standard of dental training provided in other EU member states to ensure that they do, in reality, guarantee equivalent competency and standards of care provided by dental professionals from other states*."*

The Faculty of General Dental Practice (UK) (FGDP) also raised the issue of consistent standards stating:

> *"…*The ability of dentists and dental care professionals who trained outside the UK to register with the General Dental Council and practise dentistry in the UK, based on different standards to those required of UK practitioners for registration and practice, can be concerning if the standard to which an individual trained in a particular area of practice is considered lower, and if that individual is not restricted from practising in that particular area*."*

Comments were also received in relation to training being needed for professionals coming to work in the UK for example in relation to UK law and professional ethics.

The GPhC responded that in their view:

> *"…*The revised Directive continues to make explicit that the list of activities in Article 45(2) is a minimum set of activities that holders of the Directive compliant pharmacy qualifications must be able to gain access to and pursue. Other activities can be pursued in addition to these. No amendments appear to have been made to the Pharmacy Order and we don't think that any are required*."*

The General Medical Council (GMC) raised concerns around the potential implementation of the new partial exemptions provision, which allows for exemptions to be granted on a case by case basis from parts of specialist medical training for certain professionals (if they have already previously obtained a professional qualification in another specialty).

Where appropriate the points made above have been picked up in the 'Conclusion' chapter of this document.

Q4. Do you have any comments on the Department's draft European Qualifications (Health and Social Care Professions) Regulations 2015 in relation to the EPC? Are there any further consequential amendments that you think need to be made?

Q5. Do you think there are any potential issues with the introduction of the EPC in relation to the health care professions that have been selected by the Commission?

Questions 4 and 5 sought respondents' views on the introduction of the EPC for nurses, pharmacists and physiotherapists. As set out in the consultation document, the EPC is an electronic 'card' which will store proof of qualification and additional information needed to gain recognition of a person's qualification in other Member States. The detail of how it will work is contained in a Commission Implementing Act which is a legal document. The domestic legislative framework for the introduction of the EPC is set out in both the BEIS regulations (for general systems professionals) and the Department's regulations (for automatic recognition professionals). Key points to note are:

- The EPC is an optional route to recognition for professionals (who hold qualifications in the relevant professions). Professionals can still choose to follow the existing route to recognition; and
-
- The issuance of an EPC does not give that individual automatic access to the profession (except in the case of temporary and occasional services where the EPC would replace the self-declaration which is currently required).

Summary of responses to question 4: comments on draft legislation

Response	**Number of respondents**	**Percentage (rounded)**
Yes	10	29%
No	13	37%
Don't Know	2	5%
Not Answered	10	29%
Total	**35**	**100%**

There was a relatively even split between the number of respondents who answered this question with a 'Yes' (10) and those that answered 'No' (13). A similar number (10) did not answer the question at all whilst a small number (two) selected 'Don't Know'.

Summary of responses to question 5: potential issues with the selected professions

Response	Number of respondents	Percentage (rounded)
Yes	19	54%
No	5	14%
Don't Know	4	12%
Not Answered	7	20%
Total	**35**	**100%**

A small majority of respondents (19) felt that there were some potential issues with the introduction of the EPC for the selected professions with only five respondents not anticipating any issues. There were seven respondents in the 'Don't Know' category and a further four who did not answer the question at all.

A significant number of respondents made additional comments under these two questions, although they did not all relate directly to the questions. Some set out more general points about the EPC.

There was clear support for the EPC from the FGDP who said:

> *"…*FGDP (UK) supports the introduction of the European Professional Card as a means of enabling healthcare professionals to demonstrate proof of their qualification to national regulators. We would welcome the inclusion of Dentists and Dental Care Professionals in the next wave of the EPC's roll out*."*

The Health and Care Professions Council (HCPC) were content with the drafting of the regulations in relation to the EPC stating:

> *"…*We consider that the proposed amendments to our Order and accompanying Rules set out in the draft regulations cover any resultant issues in relation to the EPC. This includes: allowing a visiting health professional from a relevant European State who holds an EPC to practise in the UK on a temporary and occasional basis; enabling our Council to set reasonable and proportionate fees for processing and /or issuing EPCs; and providing appeal provisions for the issuing, extension or revocation of an EPC or the failure by the Registrar to make a decision within the required time limits*."*

A number of respondents did however express concerns about the benefits of the EPC and how it could be operated effectively and ensure that there were no increased risks to patient safety. Particular concerns were raised by a number of respondents in relation to the EPC for temporary and occasional services. The Nursing and Midwifery Council (NMC) raised the issue of temporary and occasional service provision highlighting it as a potential public protection risk:

> *"…*Applicants' applying for an EPC to practice on a temporary and occasional basis who benefit from automatic recognition will have their EPC issued by their home member state. Essentially, this means that the applicant's home competent authority will authorise

them to practice in the UK and not the NMC. As a matter of principle we believe that, as the UK competent authority, we should be in a position to be able to authorise the practice in the UK of all EU trained migrants*".*

The GPhC were also concerned about temporary and occasional service and requested the inclusion of a provision that would:

> *"…*enable us to refuse to register an individual who has been issued with an EPC for T&O service provisions by their home Member State in circumstances where we have concerns that the EPC has been issued in error*."*

A number of other comments were made under these two questions including:

- the need for the EPC to be reviewed on an annual basis and before it is extended to any additional professions;
- the issue that the EPC was unlikely to be widely known about in the NHS or by private employers;
- concerns around a potential increase in registration fees for nurses due to costs incurred by regulators in processing applications; and
- concerns around the Commission's third party verification portal being confusing given the regulators in the UK already have searchable registers and the potential for fraud if EPC certificates are printed, or if other states were not as well-resourced or experienced in detecting fraud as the UK

Where appropriate the points made above have been picked up in the 'Conclusion' chapter of this document.

Q6. Do you agree with the Department's interpretation of what should constitute an alert in relation to healthcare professionals?

This new alert mechanism applies to all professionals exercising activities that have patient safety implications such as health and care professionals. It will be set up by the EC using the IMI system. The Department considers that any restrictions on a professional's practice with potential patient safety implications should be notified to other Member States by way of the alert mechanism rather than by more informal channels that also exist. It may be possible for the regulators to exercise some discretion when making decisions as long so they ensure that any decisions are made in line with the objectives of the alert mechanism which is to protect patients.

Response	**Number of respondents**	**Percentage (rounded)**
Yes	21	60%
No	7	20%
Don't Know	4	11%
Not Answered	3	9%
Total	**35**	**100%**

The majority of respondents (21) were in favour of the Department's interpretation of what should constitute an alert with only seven disagreeing. There were four responses in the 'Don't Know' category and a small number (three) who did not answer the question.

The majority of respondents, particularly the regulatory bodies, commented on how the system could work most effectively.

The NMC were supportive of the Department's approach to the alert mechanism saying:

> *"…*We welcome the Department's approach to implementing the alert mechanism and, due to the differing nature of the nine healthcare regulators' legislation, it's [the Department's] approach of allowing regulators to exercise some discretion on when to send alerts*."*

The issue of consistency and common criteria was mentioned by a number of respondents, including the response from the PSNI, which said the Department's interpretation of what should constitute as an alert was reasonable. However, it felt there needed to be assurances in regard to the robustness of other Member State Governments' and competent authorities' interpretation of an alert.

Similarly the FGDP welcomed the alert mechanism in the interests of patient safety but added that:

> *"…*We note the Department's intention to argue that the legislation should not prescribe exactly which restrictions on practice should trigger an alert, and request confirmation that the Department will nonetheless ensure that national regulators will be using common criteria, as otherwise the system will lack credibility*."*

The HCPC supported the Department's interpretation and also raised the issue of administrative errors compared to fitness-to-practice (FTP) matters, stating that it was not appropriate for an alert to be issued for administrative matters such as registration not being renewed on time. It stated:

> *"…*We do not think that it would be appropriate in all instances to send an alert for non-FTP related matters. We contend that administratively removing a professional in such instances would not constitute a prohibition on practice of the kind envisaged by the revised Directive. Such an alert would require us to send many hundreds of alerts at each renewal period which would subsequently be revoked within a short time period*."*

A health and social care professional felt that the interpretation was less than was necessary to protect patients and a further alert was required to record matters of significant concern under investigation. Although this could cause inconvenience to individuals subsequently cleared of malpractice, it would ensure a higher level of patient protection and the *"…*vast majority of professionals with no current concerns should not be inconvenienced by this needed assurance for patient safety*".*

The majority of responses from the regulatory bodies also highlighted the principles that have been developed through the Alliance of UK Health Regulators on Europe (AURE). The group has agreed basic principles that will underpin any decision relating to when an alert is issued.

Where appropriate the points made above have been picked up in the 'Conclusion' chapter of this document.

Q7. Do you think it would be helpful for the Department to provide healthcare specific guidance for the regulatory bodies to complement the BEIS guidance?

Q8. Is there anything that you would like us to include in healthcare specific guidance?

BEIS has published cross sector guidance which gives an overview of the cross cutting changes such as the EPC and the alert mechanism. Due to the complexities of some of the changes to the Directive, the Department was considering whether any additional guidance documents for the health and care regulators would be appropriate. We therefore sought views on this as part of the consultation.

Summary of responses to question 7: would guidance be helpful?

Response	Number of respondents	Percentage (rounded)
Yes	26	74%
No	2	6%
Don't Know	4	11%
Not Answered	3	9%
Total	**35**	**100%**

The majority of respondents (26) answered 'Yes' to this question although only a small number of additional comments were made. Only two answered 'No', with four in the 'Don't Know' category. Three respondents did not answer the question.

Summary of responses to question 8: topics to include in guidance

Response	Number of respondents	Percentage (rounded)
Yes	20	57%
No	4	12%
Don't Know	5	14%
Not Answered	6	17%
Total	**35**	**100%**

A significant number of respondents (20) answered 'Yes' to this question, and made suggestions on what needed to be included in any healthcare specific guidance. Only four respondents answered 'No' with a further five in the 'Don't Know' category. Six respondents did not answer this question.

The main reasons given in support of healthcare specific guidance included that it:

- would provide clarification;
- would complement BEIS guidance; and
- would help to ensure patient safety.

The main topics suggested for inclusion covered:

- the differences between medical specialties across Member States and mutual recognition
- the EPC
- the alert mechanism
- partial access
- the provision of temporary and occasional services
- conditions for recognition of qualifications
- common training frameworks
- language controls
- how to interpret terms such as ‘patient safety’

Of those who did not think it necessary for the Department to produce health specific guidance, one respondent suggested that the existing EU Code of Conduct would be sufficient as long as it continued to be fit for purpose.

The issue of health specific guidance is picked up in the ‘Conclusion’ chapter of this document.

Q9. Are there any protected characteristics that you feel may be affected, either positively or negatively, by these changes?

The general equality duty set out in the Equality Act 2010 requires public authorities, in the exercise of their functions, to have due regard to the need to:

- eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Act;
- advance equality of opportunity between people who share a protected characteristic and those who do not ; and
- foster good relations between people who share a protected characteristic and those who do not.

The protected characteristics are age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex and sexual orientation, with marriage and civil partnership being a protected characteristic under point one above.

As set out in the consultation document, the revised Directive will impact on those professionals wanting to move around within the EU. The majority of changes should make it easier for individuals to move from Member State to Member State and we anticipate that it will not significantly affect any of the protected characteristics.

Response	**Number of respondents**	**Percentage (rounded)**
Yes	6	17%
No	16	46%
Don't Know	5	14%
Not Answered	8	23%
Total	**35**	**100%**

Only six respondents answered 'Yes' to this question with 16 answering 'No' and five respondents selecting 'Don't Know'. Eight respondents did not answer the question.

Only a small number of additional comments were received. These included comments from the GMC who felt that the revised Directive would lead to differences between European Economic Area (EEA) and other non-UK national doctors in relation to their routes to registration. They gave the example that EEA nationals who hold American or Canadian primary medical qualifications would not meet the amended requirements in the Directive of a minimum of 5,500 hours and five years for basic medical training. However the numbers affected by this change are likely to be very small and the GMC report that:

> *"…*We have carried out an equality analysis to understand the potential impact of the policy on doctors sharing protected characteristics. This showed that since 2010 we have registered fewer than 10 doctors per year who would be affected by the change to the BMT (basic medical training)

requirements. The majority of this cohort identifies as White but there is no strong correlation in relation to nationality, age and gender."

The British Medical Association (BMA) considered that there were unlikely to be any equality impacts on the UK because of the changes, but recommended regular impact assessments.

Issues raised by respondents who considered the changes may have an equalities impact were in the following areas:

- partial access
- a comment about discrimination due to skin colour
- a concern that graduate numbers would be reduced which would affect a certain age group

Q10. Are there any potential monetary impacts (either positive or negative) that you think we need to be aware of?

The Department considered the impact of the changes which are specific to the sectoral health professions (listed in Annex A of the consultation document) and surmised that there was not likely to be a large impact on business from any of the amendments. We sought further comments from respondents on potential impacts as part of the consultation.

Response	**Number of respondents**	**Percentage (rounded)**
Yes	17	49%
No	4	11%
Don't Know	6	17%
Not Answered	8	23%
Total	**35**	**100%**

Almost half of the respondents, 17, answered 'Yes' with only four stating there were no potential monetary impacts. Six respondents answered with a 'Don't Know' and eight did not answer the question at all.

Although the potential impact of the cross sector changes has been assessed by BEIS as part of its consultation, the majority of comments in relation to impact were on these cross sector changes and the following points were raised a number of times by respondents:

- the cost of the alert mechanism
- the cost of implementing the EPC
- the potential for fee increases by regulators

Other potential impacts also highlighted included:

- costs for minority groups
- IT infrastructure – who would pay for this, local or nationally funded
- quality issue – may seem cheaper now but long term could be negative to rectify new problems
- cost issues for temporary and occasional workers

Conclusion

The Department is grateful to those who responded, taking the time to provide wide ranging comments on this consultation. Some of the concerns raised are in relation to details that have been agreed in the Directive and therefore cannot be altered in its implementation by the Department.

Concerns have been expressed that the Directive unduly constrains the ability of regulatory bodies to carry out robust checks of both the clinical and language skills of health professionals from the EEA seeking to practice in the UK. The Governments is mindful of these concerns, and the UK's decision to exit the European Union will provide an opportunity to review the adequacy of checks on the skills and competence of overseas health professionals that are currently carried out.

Amendments to the regulations

As a result of the comments made during the consultation process a number of changes have been made to the drafting of the European Qualifications (Health and Social Care Professions) Regulations 2016. Some of the changes that have been made are set out below:

- a number of minor and technical corrections;
- the new provisions will not apply to Switzerland as they are not currently signed up to the revised Directive;
- the new requirement in relation to having to provide an attestation that the individual has no criminal convictions has been revised; and
- changes to the wording of the new provisions for doctors and pharmacists on professional traineeships.

Pharmacy practical traineeships

As set out on pages 10-11, the responses to question 2 on the timing of the traineeship element of pharmacy training were fairly equally weighted. Arguments for practical training to take place either during the course or at the end of the course show that they both offer potential benefits to students.

It seems sensible that a course that integrates practical training both during and after the course will provide the best experience for students. It is for individual training organisations to decide how they wish to organise and set their training. The approach in the Directive is likely to have been taken to ensure that pharmacy training institutions in all EU Member States are able to make individual decisions about when it is most appropriate to undertake a practical traineeship. It should also be noted that the Directive sets out only the minimum amount of practical training and in the UK the requirement is usually 52 weeks of pharmacist pre-registration training which is approved by the GPhC.

Partial exemptions provision

The Department has been working with the GMC and other key stakeholders for a period of time to understand any potential impacts on current processes of implementing this provision and to ensure that any adverse effects are minimised.

European Professional Card

The Department will continue to push for the Commission to honour its commitment to carry out an early review of the EPC process and for any review to incorporate the views and experiences of those who will be using the system such as the regulatory bodies.

A review will ensure that any issues are captured and can then be addressed in a timely manner before it is rolled out to any additional professions.

Alert mechanism

As set out in the consultation document the Department does not plan to list which decisions would trigger an alert in the healthcare regulators' legislation because this would be too prescriptive and too inflexible. We welcome the principles that have been developed by the AURE and note that they were also viewed positively when shared with the EC. The Professional Standards Authority for Health and Social Care (PSA) also expressed support for the principles in their consultation response. The principles should mean that the regulatory bodies in the UK are all following a consistent approach.

We would suggest that these principles are also shared with the regulatory bodies' counterparts in other Member States to increase consistency of approach further.

Healthcare specific guidance

The Department sought views on whether it would be useful to produce additional guidance with a health specific focus. BEIS has published guidance which covers the cross sector changes. The cross sector changes are mainly where respondents suggested providing additional guidance. After further consideration the Department's current view is that producing health specific guidance would not provide any additional benefits. For example the EPC Implementing Act sets out the detail around processing applications.

We will however continue to monitor the implementation of the revised Directive and revisit whether additional guidance is necessary in the future.

Information is available online for example through the NHS Employers' website which sets out the changes in the Directive. There is potential need for increased awareness on the changes in the Directive and we will consider what more can be done in light of the comments received. We would also recommend that the regulatory bodies continue to raise awareness of the changes through their usual communication channels.

Key to Abbreviations

AURE	Alliance of UK Health Regulators on Europe
BEIS	Department for Business, Energy and Industrial Strategy
BMA	British Medical Association
EC	European Commission
EEA	European Economic Area
EPC	European Professional Card
EU	European Union
FGDP	Faculty of General Dental Practice (UK)
GMC	General Medical Council
GPhC	General Pharmaceutical Council
IMI	Internal Market Information
IT	Information Technology
HCPC	Health and Care Professions Council
The Directive	Mutual Recognition of Professional Qualifications Directive
NHS	National Health Service
NMC	Nursing and Midwifery Council
PDA	Pharmacists' Defence Association
PSA	Professional Standards Authority for Health and Social Care
PSNI	Pharmaceutical Society of Northern Ireland
RPS	Royal Pharmaceutical Society
T&O	Temporary and Occasional
the Regulations	The European Qualifications (Health and Social Care Professions) Regulations 2016
the Department	The Department of Health
UK	United Kingdom