



Department  
of Health

# Transposition of revised Mutual Recognition of Professional Qualifications (MRPQ) Directive 2005/36/EC

Amendments to health and care regulators' legislation

**A CONSULTATION ON THE HEALTH SPECIFIC AMENDMENTS TO THE DIRECTIVE**

**Title:****Transposition of revised Mutual Recognition of Professional Qualifications (MRPQ) Directive 2005/36/EC – Amendments to health and care regulators’ legislation**

a consultation on the health specific amendments to the Directive

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# Executive summary

By 2020 there will be 16 million more jobs in the EU requiring highly skilled professionals<sup>1</sup> such as healthcare professionals. To meet this demand, it is essential that the mechanism to recognise qualifications of mobile professionals is fast and effective.

The introduction of the original Mutual Recognition of Professional Qualifications (MRPQ) Directive (the Directive) made it easier for skilled professionals, including healthcare professionals, to move around Europe. This benefits the UK by giving us greater access to a skilled labour market and by allowing UK residents more freedom to pursue their chosen careers across the EU. Note that this Directive only covers those professionals who are fully qualified to practise a profession in one Member State and who wish to practise the same profession in another Member State.

The recent revision of the Directive has introduced important changes that should speed up the process and bring in additional safeguards. In addition, there have been helpful clarifications around the application of language controls for professions with patient safety concerns. The Department for Business, Innovation and Skills (BIS) is the lead Department for the Directive which covers a number of different professions, including those from the healthcare sector.

BIS have undertaken two consultations focusing on the changes that impact on all professions (including healthcare professions) covered by the Directive. The results of these consultations can be found on the Gov.UK website<sup>2</sup>.

The Department of Health (the Department) has been working closely with officials in BIS throughout the implementation period to ensure that the changes do not adversely affect patient safety. Where the regulators still have concerns in relation to the implementation of provisions (mainly around the provisions covered by the BIS consultation) we will continue to work with the regulators to address these.

The focus of this document is to seek views on the drafting of the Regulations which transpose the Directive for the UK health and care professions where amendments to their governing UK primary and secondary legislation are necessary. This document also seeks views on the proposals to produce Department guidance and comments on any potential impacts of implementation. This consultation has been issued on behalf of the four UK Health Departments and the outcome will be reported to all UK health Ministers.

This consultation will run for six weeks from 10 December 2015 to 20 January 2016. It is the culmination of more than two years of informal consultation and engagement with 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 to achieve the intention of the Directive whilst ensuring that patient safety is maintained.

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<sup>1</sup> European Commission memo, 'Modernisation of the Professional Qualifications Directive – frequently asked questions', 9 October 2013 [http://europa.eu/rapid/press-release\\_MEMO-13-867\\_en.htm](http://europa.eu/rapid/press-release_MEMO-13-867_en.htm)

<sup>2</sup> <https://www.gov.uk/government/consultations/mutual-recognition-of-professional-qualifications-revised-directive>.

# Introduction

## Background

1. The Mutual Recognition of Professional Qualifications (MRPQ) Directive 2005/36/EC (the Directive) originally came into force in 2007. The Directive replaced 15 existing Directives in the field of recognition of professional qualifications, providing the first comprehensive modernisation of the EU system since its introduction over 40 years ago. In 2010, the European Commission announced its plans to carry out a review of the Directive to ensure greater mobility through a more overt and streamlined recognition of professional qualifications process and by removing any unnecessary barriers to free movement.
2. The Commission subsequently conducted a major re-evaluation of the 2005/36/EC Directive. As part of this revision all Member States including the UK were involved in detailed negotiations which, in terms of health and care professions, included ensuring that the health regulators' views were fed back to the Commission. The revised text<sup>3</sup> was formally agreed by the European Parliament in November 2013, becoming effective from January 2014 (as amended by Directive 2013/55/EU). The two year transposition period means that all Member States including the UK must transpose the amendments to the Directive into domestic law by 18 January 2016, when it comes into force.
3. This current revision of the Directive is an EU Single Market Act priority designed to facilitate greater freedom of movement (one of the four fundamental freedoms of the European Union) for professionals wanting to work across the European Union. It enables individual professionals to market their skills in other Member States on a temporary or permanent basis. It does this by creating more efficient and transparent recognition of professional qualifications with a particular focus on using modern technologies to support mutual assistance between Member States.
4. This will benefit individual professionals in terms of freedom of movement and benefit business, consumers and the EU as a whole, by filling skills gaps and enhancing economic growth. The system will help make labour markets more flexible, further liberalise the provision of services, encourage more automatic recognition of qualifications, and simplify administrative procedures. There are also indirect benefits for the UK economy through UK professionals working overseas gaining wider experience and skills.

## The Directive

5. The Directive provides a framework for recognising professional qualifications, with the aim of enabling individuals to work on a permanent or temporary basis across other Member States.
6. The Directive includes provisions on:
  - Knowledge of languages
  - Minimum standards of training
  - Temporary service provision

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<sup>3</sup> [http://ec.europa.eu/growth/single-market/services/free-movement-professionals/policy/legislation/index\\_en.htm](http://ec.europa.eu/growth/single-market/services/free-movement-professionals/policy/legislation/index_en.htm)

- Conditions for recognition
- Recognition of professional traineeships
- Compensation measures

7. The Directive also includes a number of new provisions, namely:

- The introduction of the European Professional Card (EPC) which is an electronic 'card' which certain professionals can apply for as proof of recognition of qualification.
- A new provision enabling partial access to regulated professions for certain professionals.
- The introduction of a Europe-wide alert mechanism to enhance patient safety across the EU.
- The possibility to introduce automatic recognition for certain professions based on common training frameworks and common training principles.

## The role of the health and care regulators

8. In the UK, statutorily regulated health and social care professionals have to be registered with, and show that they meet the standards of, the relevant regulatory body, in order to practise their profession. The regulators control access to regulated professions, professional and vocational titles and professional activities which require specific qualifications, and are subject to national law. The European Commission term these organisations the 'competent authorities'.

## Automatic system vs general system

9. There are two different systems for recognising qualifications: the automatic system and the general system. This approach is unchanged in the revised Directive.

*Automatic System* - This does not mean that a professional's qualification is automatically accepted. It simply means that the relevant regulators have a framework for dealing with the application. The automatic system has harmonised education and training for the following professions relevant to health: doctors, dentists, general care nurses, midwives and pharmacists. If a person holding one of these titles has a qualification listed in Annex V<sup>4</sup> of the Directive which complies with the minimum standards under the Directive<sup>5</sup>, or has acquired rights under article 23 of the Directive<sup>6</sup>, they are entitled to have their qualifications recognised automatically by a host Member State. For this class of person, it is not possible to require any further qualifications or competency assessments before registration with a regulatory body.

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<sup>4</sup> Annex V is an annex of the Directive which lists the professions that benefit from recognition on the basis of coordination of the minimum training conditions and are therefore part of the 'automatic system'.

<sup>5</sup> See article 21 of the Directive - [http://ec.europa.eu/growth/single-market/services/free-movement-professionals/policy/legislation/index\\_en.htm](http://ec.europa.eu/growth/single-market/services/free-movement-professionals/policy/legislation/index_en.htm)

<sup>6</sup> An acquired right is where access to the profession has changed due to entry requirements being revised but a professional with a qualification that is no longer sufficient for entry into the profession still has 'acquired rights' to the profession.

*General System* - All other health professions will fall under the general system. In addition, some individuals who have a qualification for one of the sectoral professions<sup>7</sup> may not be included in the Annex V list of professions covered by automatic recognition. Under the general system Member States need to consider a migrant's qualifications on a case by case basis to determine whether their qualifications and experience meet the same standard as that required in the UK for that profession. If they do, then they are entitled to have their qualifications recognised. If they do not meet the required standard then the Member State can impose compensation measures by way of an aptitude test or adaptation period. If the migrant passes the test, or successfully completes an adaptation period, they are entitled to have their qualifications recognised<sup>8</sup>.

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<sup>7</sup> These are the professions for which the minimum training conditions were harmonised at European Community level and are called the sectoral professions. In terms of health the professions included are doctors, nurses responsible for general care, dental practitioners, midwives and pharmacists.

<sup>8</sup> See article 5 to 20 of the Directive for general system applications - [Directive 2013/55/EU](#)

# Transposition of revised Directive

## Implementing the revised Directive in the UK

10. In the UK, BIS leads on the implementation of the Directive. BIS has produced draft Regulations, the *European Union (Recognition of Professional Qualifications) Regulations 2015*<sup>9</sup>, which apply to all general systems professionals (which include the sectoral professions where professionals do not meet the harmonised minimum standards of training). The BIS Regulations also cover a number of provisions that affect all professionals regardless of whether they follow the automatic or general systems such as the Alert Mechanism and Partial Access.
11. BIS conducted a 3 month consultation from 14 August 2014 to the 6 November 2014 which set out an overview of the new provisions of the Directive and the plan for transposition. They considered the responses to the consultation and published a government response in March 2015 together with their overview of the next steps<sup>10</sup>. The consultation asked for views on a range of areas: the introduction of the European Professional Card (EPC); partial access; temporary or occasional provision of service; language controls; conditions for recognition; compensation measures; a common training framework; professional traineeships; exchange of or access to information; and the Internal Market Information (IMI) system<sup>11</sup>. In spring 2015 BIS conducted a further consultation on the draft regulations covering the cross sector provisions and draft guidance relating to these provisions.
12. The Department is responsible for transposing those measures which relate specifically to the sectoral health professions (doctors, dentists, general care nurses, midwives and pharmacists) and making sure that the required amendments are made to their domestic legislation and it is these changes that are discussed in more detail in this consultation document. In addition, this document discusses the potential impacts of the key cross-sector provisions (consulted on by BIS) which affect the health and care professions. As set out above, the Directive covers only those professionals who are fully qualified to practise a profession in one Member State and who wish to practise the same profession in another Member State. The professionals covered are still required to adhere to the standards of competence and behaviours set by the regulatory bodies in the Member State in which they are practising.

## Language controls for health and care professions

13. Following the clarifications contained in the revised Directive around the application of language controls for professions with patient safety concerns the Department has given the power, through legislation, to a number of the health and care professional regulators (General Medical Council (GMC), Nursing and Midwifery Council (NMC), General Pharmaceutical Council (GPhC), General Dental Council (GDC) and Pharmaceutical

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<sup>9</sup> [Draft Statutory Instrument: European Union \(Recognition of Professional Qualifications\) Regulations 2015](#) please note that these are no longer the latest version of the draft regulations as they have been updated post consultation.

<sup>10</sup> [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/420691/bis-15-252-mutual-recognition-of-professional-qualifications-revised-directive-government-response.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/420691/bis-15-252-mutual-recognition-of-professional-qualifications-revised-directive-government-response.pdf)

<sup>11</sup> The IMI system is a Commission led online system where Member States can exchange information relating to the movement of professionals



Society of Northern Ireland (PSNI)<sup>12</sup> to introduce proportionate language controls for EEA applicants. The power also allows the regulators to consider lack of proficiency in English as grounds for bringing a fitness to practise case against a regulated professional<sup>13</sup>.

14. These powers enable the regulators to carry out proportionate checks on professionals where there is concern around their English language capability. These will help strengthen provisions which already exist to prevent patients from being put at risk of harm from professionals who do not have the necessary knowledge of English language.
15. In addition to these changes around the application of language controls for health and care professions, the Government will shortly introduce new legislation requiring every public sector worker employed in a public-facing role to speak fluent English which will mean that all public sector organisations must ensure that staff can communicate effectively with the public.

## The Implementing Regulations

16. Accompanying this consultation is a copy of the Department's draft regulations, the *European Qualifications (Health and Social Care Professions) Regulations 2015*.<sup>14</sup> These implement the revised Directive into domestic health and care legislation where appropriate. The Regulations are made under the powers in section 2(2) of the European Communities Act 1972. Using these powers, it is possible to amend primary legislation (e.g. the Medical Act) and secondary legislation (e.g. the Nursing and Midwifery Order or the regulators' Rules).
17. Whilst the changes which affect all regulated health and care professions not just the sectoral professions, are set out in the BIS regulations, such as the alert mechanism<sup>15</sup>. The Department's Regulations do make a number of consequential amendments relating to the cross-sector amendments and make reference to the BIS Regulations in the relevant places.

## The Devolved Administrations

18. The *European Qualifications (Health and Social Care Professions) Regulations 2015* make the necessary changes to domestic legislation in relation to the health and social care professions in the UK including those whose regulation is devolved to Scotland, Wales and Northern Ireland. The Department of Health in England has agreed with the devolved administrations to consult on and transpose the amendments for all four countries. In doing

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<sup>12</sup> The PSNI is working with the Department of Health, Social Services and Public Safety in Northern Ireland and DH England to develop a timetable for commencement.

<sup>13</sup> It should be noted that the GDC is awaiting other legislative amendments to its fitness to practise regime in order to allow the language elements to commence.

<sup>14</sup> Please note that these regulations are still in draft form and are not the final version.

<sup>15</sup> Other than provisions around alert mechanism appeals which are covered in the DH regulations

so we have worked closely with the devolved administrations and will continue to do so throughout the remainder of the transposition period.

## Stakeholder engagement

19. We have been engaging with key stakeholders throughout the transposition and earlier negotiating process, in particular with the UK health and care regulatory bodies. This is to ensure that the implementation of the revised Directive does not negatively impact on patient safety and to avoid creating any unnecessary burden for them. This written consultation is a continuation of this activity.
20. As part of this engagement we have met with each regulator individually and in groups to discuss implementation and any concerns they may have, and to work through the required changes to their governing legislation.

# Amendments to the Directive

21. This section sets out the changes that are contained in the revised Directive. As mentioned at the start of this consultation document the Department is consulting on the changes that specifically affect the sectoral health professions (doctors, dentists, general care nurses, midwives and pharmacists) and more specifically professionals who benefit from the automatic system. These are discussed below. However as a number of the cross-cutting changes are likely to impact on the health and care regulators and subsequently on health and care professionals we have also included them in our consultation.
22. The Department's Regulations which accompany this consultation cover both the specific sectoral changes and reference the cross-cutting amendments where appropriate.

**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?**

## Changes specific to health professions under the automatic system

23. Professions benefiting from the automatic system of recognition are those for which the minimum training conditions have been harmonised at European Community level. In terms of health the relevant professions are doctors, dentists, general care nurses, midwives and pharmacists (the sectoral professions).
24. The revised Directive makes a number of specific changes in relation to these health professions. In summary, the majority of these changes are small clarifications to the process of recognition of qualifications aimed at increasing the mobility of professionals and individuals applying to study for professional qualifications across the EU.
25. A full list of amendments can be found at Annex A. However a summary of the key changes is set out below.

### **Doctors**

- The key changes relating to doctors are around the minimum length of basic medical training. The Directive now states that the length must be at least 5 years of study and at least 5,500 hours. This is a change from 6 years or 5,500 hours previously. The minimum length of basic medical training in the UK is already in line with these changes.
- The revised Directive introduces a new provision which allows for partial exemptions from parts of specialist medical training for certain professionals. This means that, under certain circumstances, where a professional has already covered the relevant part of training in a previously attained professional qualification in any relevant European states the GMC can consider applying a partial exemption on a case by case basis.

- There are changes in relation to acquired rights<sup>16</sup> which mean that acquired rights are granted to professionals who have specialist medical qualifications awarded in Italy whose training started after 31/12/1983 and before 01/01/1991. This will mean that these professionals will be able to access the quicker automatic system route to recognition.

## **Nurses**

- The entry requirements into nurse training have been amended from just a 12 year educational route to a two tiered system of both 10 and 12 years education routes. This means that if you have 10 years of general education you may be able to access a vocational training programme for nursing whereas if you have 12 years of general education you may be able to access university or higher education institution level training programmes. This amendment was made as some Member States still have vocational routes to nursing. However, in the UK we have moved to degree level nursing and there is currently no intention to change this. We do not expect there to be any impact in terms of the quality of nurses coming in from other Member States as both vocational and higher education level training must meet the same standards which are set out in the Directive.
- The minimum length of training for nurses must now be 3 years and at least 4,600 hours which is a change from 3 years or 4,600 hours previously. There are also changes to the competencies which a nurse should acquire through their training. The NMC undertook a mapping exercise to ensure that pre-registration nurse training in the UK already covers the competencies added to the revised Directive.
- There are a number of changes in relation to nurses who have trained in Poland and Romania. These changes introduce an upgrade programme in relation to Polish nurses and amendments which introduce two additional qualifications that, together with the required period of experience practising as a nurse, would qualify nurses trained in Romania for acquired rights. There are also changes to the period of experience required in addition to formal qualifications which has changed from 5 consecutive years in the last 7 to 3 consecutive years in the last 5.

## **Midwives**

- The entry requirement for midwifery training has been increased from 10 years of general education to 12 years. The UK system is already in line with this change.
- One of the criteria for automatic recognition of midwifery qualifications has also been amended to require a least three years full time training with the addition of consisting of at least 4,600 hours of theoretical and practical training. Previously the requirement in the Directive only referenced three years.
- There have also been a number of minor amendments to the section which sets out what knowledge and skills midwives should have obtained as part of their training. The NMC undertook a mapping exercise to ensure that pre-registration midwifery training in the UK already covers the competencies added to the revised Directive.

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<sup>16</sup> 'Acquired rights' is where access to the profession has changed due to the entry requirements being revised. If an applicant holds a qualification that was regarded as sufficient at the time of the award for entry into the profession, they are classed as having acquired rights under the Directive.

### **Dental practitioners**

- An additional requirement has been introduced that the 5 years of study must comprise at least 5,000 hours of full-time theoretical and practical training.
- A new provision has been included that provides additional acquired rights as a consequence of the more stringent minimum standards required for basic dental training. This will mean that professionals who hold one of the qualifications listed in Annex V of the Directive will still be able to apply for automatic recognition from 18 January 2016 even though the minimum standards are now different.

### **Pharmacists** (these changes will apply to pharmacists both in Great Britain and in Northern Ireland)

- Changes have been made to the section on the training of pharmacists, in particular the paragraph in the Directive (Article 44, paragraph 2) which sets out when a trainee needs to complete the required period of practical training. Previously the European Commission pharmaceutical advisory committee had advised that the 6 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'.

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

- There are also a number of changes to the activities listed as being undertaken by a pharmacist including the addition of:
  - distribution and dispensing, of the required quality;
  - providing 'information on the appropriate use of medicinal products';
  - a requirement to access the following additional activities to be pursued by pharmacists:
    - reporting of adverse reactions to pharmaceutical products to the Competent Authorities;
    - personalised support for patients who administer their medication;
    - contribution to local or national public health campaigns.

We understand that these additions are already covered by pharmacy training in the UK.

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

## Changes that cover professions from across sectors

26. There are a number of changes that affect professions from a number of sectors (for example teachers and architects) which BIS have consulted on<sup>17</sup>. However, where they also impact on health and care we consider it appropriate to discuss them further here.
27. The key cross-cutting changes are:
- the introduction of the European Professional Card
  - the introduction of an alert mechanism for professions with patient safety risks
  - the provision of partial access to a profession.
28. The BIS consultation analysis report published on 26 March 2015<sup>18</sup> acknowledged that there were some remaining concerns around some of the cross-cutting provisions. Comments made during the exercise have informed the drafting of the BIS Regulations and their guidance.
29. Below we have provided a summary of the cross cutting amendments which impact on health and care professions.

### The European Professional Card (EPC)

30. The EPC is an electronic 'card' (transmitted via the Commission's IMI system) which will store proof of qualification and additional information needed to gain recognition of qualification in other Member States. It has been designed to allow professionals who hold one to move more freely and quickly around the EU and the detail of how it will work is contained in a Commission Implementing Act<sup>19</sup>. The following health professions have been chosen by the Commission to be included in the first wave of professions to have the EPC introduced:
- Nurses responsible for general care
  - Pharmacists
  - Physiotherapists
31. The BIS Regulations will set out the framework for the EPC (based on the Implementing Act) and the process the regulators will need to follow with the Department's Regulations making consequential amendments and amendments relating to automatic recognition professionals regarding the chosen health professions. Key points to note are:
- a. The EPC is an optional route to recognition for professionals (who hold qualifications in the relevant professions). Professionals can still chose to follow the existing route to recognition.
  - b. 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 required).

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<sup>17</sup> <https://www.gov.uk/government/consultations/mutual-recognition-of-professional-qualifications-revised-directive>

<sup>18</sup> <https://www.gov.uk/government/consultations/mutual-recognition-of-professional-qualifications-revised-directive>

<sup>19</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R0983&from=EN>

- c. In relation to professionals working on a temporary and occasional basis the EPC will not be up for renewal for 18 months. This differs from the current temporary and occasional service provisions set out in the Directive where the declaration must be considered for renewal after 12 months.

**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?**

### **Alert Mechanism**

32. The revised Directive introduces a new alert mechanism and a requirement for Member States to inform other Member States if a professional has been restricted or prohibited to practise. This new alert mechanism applies to all professionals exercising activities that have patient safety implications such as health and care professionals and will be set up by the European Commission using the IMI system.
33. The aim of the alert mechanism is to ensure that all Member States are made aware of any restrictions on an individual's practice and therefore make evidence based decisions on whether to allow an individual to practise in their country. The Department would argue 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 as they ensure that any decisions made are in line with the objectives of the alert mechanism, which is to protect patients. The Department does not plan to list which decisions would trigger an alert in the healthcare regulators legislation as this would be too prescriptive.

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

### **Partial Access**

34. This is a new provision in the Directive which allows certain professionals to apply for partial access to a profession in a host Member State where they have the appropriate qualifications in their home Member State. The professional activity for which partial access is sought would need to be separated from other activities falling within the regulated profession. The healthcare regulators have a duty to consider partial access applications on a case by case basis. However, they are able to reject the applications if they do not fall under the required criteria or for overriding reasons of general interest, for example patient safety.
35. The legislative provisions relating to partial access are contained in the BIS Regulations.

## **Temporary and occasional service provision**

36. Under the Directive professionals are able to apply to work in other Member States on a temporary and occasional basis. This is not a new provision. However, there are a number of amendments to this section including an individual having access to the relevant profession in the entire territory of the UK once working on a temporary basis in one of the UK territories. However, this change is only relevant to those professions that are devolved to Wales, Scotland and Northern Ireland such as pharmacists (in the case of Northern Ireland) and social workers.

## **Conditions for recognition of qualifications**

37. The conditions for recognition of qualifications have been amended. The Directive sets out 5 different levels of qualifications and there have been amendments to the number of levels that the regulators have to consider. In the original Directive the regulatory body in the host Member State could reject applicants who held qualifications which were more than one level lower than the qualification required in the host Member State. The revisions to the Directive now mean that regulators have to consider individuals' qualifications even if they are more than one level below what is required in the host Member State. However regulators still have the ability to reject applications or apply compensatory measures where appropriate.

## **Common Training Frameworks**

38. The revised Directive introduces new principles around common training frameworks (CTF) and common training tests (CTT) as a new route to automatic recognition of qualifications with the aim of enabling more professionals to move around the EU. A common training framework or common training test could be set up subject to the criteria set out in the Directive (Article 49a.2 and 49b.2) of the Directive. CTFs and CTTs can only be introduced by the Commission via an Implementing Act.

39. Representative professional organisations and national professional organisations and regulators may submit suggestions for common training frameworks to the European Commission.



# DH Guidance document

40. Whilst BIS has already consulted on draft guidance<sup>20</sup> which gives an overview of the cross cutting amendments, due to the complexities of some of the changes to the Directive, the Department are considering whether any additional guidance documents for the health and care regulators would be appropriate.

41. Any guidance will be developed in light of the responses we receive to this consultation and our continued engagement with the European Commission.

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

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

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<sup>20</sup> <https://www.gov.uk/government/consultations/mutual-recognition-of-professional-qualifications-revised-directive>

# Costs and Benefits and Equality Analysis

## Equality considerations

42. The general equality duty that is 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;
  - foster good relations between people who share a protected characteristic and those who do not.
43. 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.
44. 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 will not affect any specific characteristics in particular. We do not think there are any equality impacts on the UK resulting from these changes. However, we are using this consultation to seek further views on whether there are any equality impacts that we need to consider.

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

## Costs and benefits

45. The Department has considered the impact of the changes which are specific to the sectoral health professions and surmised that there was not likely to be a large impact on business from any of the amendments.
46. The impacts of the cross-cutting amendments have been assessed by BIS<sup>21</sup>
47. As part of our consideration of the potential impact of the specific sectoral changes we looked at things such as:
- the potential administration costs to the healthcare regulators of complying/implementing the changes;
  - any potential rise or fall in the number of applicants to the UK regulators that might be expected as a result of the changes.
48. The Department liaised with the 5 regulatory bodies to whom the specific changes relate to (the General Medical Council, the Nursing and Midwifery Council, the General Dental Council, the General Pharmaceutical Council and the Pharmaceutical Society of Northern

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<sup>21</sup> <https://www.gov.uk/government/consultations/mutual-recognition-of-professional-qualifications-revised-directive>

Ireland) to test our initial estimates of where impacts might be generated and the expected scale of these. Overall, the healthcare regulators' returns supported the Department's position in that we do not, at this stage, anticipate any significant monetary costs or benefits to arise as a result of the specific sectoral amendments.

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

# Consultation questions

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?

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

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*?

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?

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

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

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

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

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

# Responding to this consultation

## Consultation process

The consultation is being run, as far as is practical, in accordance with the Cabinet Office Code of Practice on Consultations (reproduced below). The closing date for the consultation is 20 January 2016.

There is a questionnaire on the GOV.UK website which can be printed and sent by post to:

**Professional Standards,  
Room 2N09,  
Department of Health,  
Quarry House,  
Quarry Hill, Leeds,  
LS2 7UE**

Completed questionnaires can also be sent electronically by e-mail to:  
**HRDlistening@dh.gsi.gov.uk**

Alternatively you may also complete the online consultation response document at:  
<http://consultations.dh.gov.uk>

It will help us to analyse the responses if respondents fill in the online consultation response document but responses that do not follow the structure of the questionnaire will be considered equally. It would also help if responses were sent in Word format, rather than in pdf format.

## Criteria for consultation

This consultation follows the Government Code of Practice, in particular we aim:

- to formally consult at a stage where there is scope to influence the policy outcome;
- to consult for a sufficient period;
- to be clear about the consultations process in the consultation documents, what is being proposed, the scope to influence and the expected costs and benefits of the proposals;
- to ensure the consultation exercise is designed to be accessible to, and clearly targeted at, those people it is intended to reach;
- to keep the burden of consultation to a minimum to ensure consultations are effective and to obtain consultees 'buy-in' to the process;
- to analyse responses carefully and give clear feedback to participants following the consultation; and;
- to ensure officials running consultations are guided in how to run an effective consultation exercise and share what they learn from the experience.

The full text of the code of practice is on the Better Regulation website at:  
[www.bis.gov.uk/policies/better-regulation/consultation-guidance](http://www.bis.gov.uk/policies/better-regulation/consultation-guidance)

## Comments on the consultation process itself

If you have any concerns or comments which you would like to make relating specifically to the consultation process itself please contact:

Consultations Coordinator,  
Department of Health,  
2E08,  
Quarry House,  
Quarry Hill,  
Leeds,  
LS2 7UE.

Please do not send consultation responses to this address.

## Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health's Information Charter:

<https://www.gov.uk/government/organisations/department-of-health/about/personal-information-charter>

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.

## Summary of consultation responses

A summary of the response to this consultation will be made available before or alongside any further action, such as laying legislation before Parliament, and will be placed on the GOV.UK website ([www.gov.uk/dh](http://www.gov.uk/dh)).

# Annex A – changes specific to automatic systems healthcare professions

Provision in the Directive that have been amended	Description
<b>Doctors</b>	
Amendments to Article 24 – Basic Medical Training	New paragraph 2 is altered to set the minimum length of basic medical training courses to at least 5 years of study and at least 5,500 hours. This is a change from 6 years or 5,500 hours previously.
	New paragraph 2 also includes a requirement that formal qualifications may be expressed through the equivalent ECTS credits <sup>22</sup> .
	In the second sub-paragraph of paragraph 2, 'persons' is changed to 'professionals'.
Amendments to Article 25 – Specialist Medical Training	Paragraph 1 – the reference to 6 year courses is removed and new reference to Article 24(2) added.
	New paragraph 3a. refers to exemptions from parts of specialist medical training listed in 5.1.3 of Annex V offered where the relevant part of training has already been covered in a professional qualification attained by the individual in a Member State. The application of this exemption should take place on a case by case basis.
Amendments to Article 27 - Acquired rights specific to specialised doctors (Recognition of Specialist Doctors in Italy)	New paragraph 2a. grants acquired rights to professionals who have specialist medical qualifications awarded in Italy whose training started after 31/12/1983 and before 01/01/1991.
Amendments to Article 28 – Specific Training in General Medical Practice	The references to 6 years of study to length of study are changed as outlined in the amended Article 24(2).
<b>Nurses</b>	
Amendments to Article 31 – Training of Nurses Responsible for General Care	Paragraph 1 changes the entry requirements from 10 years of general education to a two tiered system of both 10 and 12 years education routes to nurse training.

<sup>22</sup> The European Credit Transfer and Accumulation System is a standard for comparing the study attainment and performance of students of higher education across the European Union and other collaborating European countries. For successfully completed studies, ECTS credits are awarded. One academic year corresponds to 60 ECTS credits that are equivalent to 1500–1800 hours of study in all countries respective of standard or qualification type and is used to facilitate transfer and progression throughout the Union.

	<p>In paragraph 3 the first sub-paragraph has been revised to include a requirement that formal qualifications may be expressed through the equivalent ECTS credits. Also the training must now be 3 years and at least 4,600 hours which is a change from the previously stated 3 years <u>or</u> 4,600 hours.</p>
	<p>In paragraph 4 - 'Theoretical training' is replaced by 'Theoretical education'.</p>
	<p>There are 3 further changes within paragraph 4:</p> <ul style="list-style-type: none"> <li>(i) it includes a reference to 'competencies' required under new article 31(7); this is a substantive new provision setting the competencies which a nurse should acquire;</li> <li>(ii) it cross refers to knowledge and skills required under paragraph 6; this has been amended to make the knowledge and skills more robust;</li> <li>(iii) the references to educational institutions are more specific.</li> </ul>
	<p>Paragraph 5, first sub-paragraph, 'knowledge and skills' is replaced by 'knowledge, skills and competences'.</p>
	<p>Paragraph 6, 'person' is replaced by 'professional'.</p>
	<p>Paragraph 6(a), 'adequate knowledge' is replaced by 'comprehensive knowledge'.</p>
	<p>Paragraph 6(b) 'sufficient' is removed before 'knowledge'.</p>
	<p>Article 31(7) sets out the competences that must be evidenced as part of the formal qualification.</p>
<p>Amendments to Article 33 – Acquired Rights Specific to Nurses Responsible for General Care (Polish Nurses)</p>	<p>Paragraph 2 requiring certain individuals to provide a certificate of previous experience is deleted.</p> <p>Paragraph 3 is updated to allow for the inclusion of an alternative 'upgrade programme' for Polish nursing qualifications.</p>
<p>Amendments to Article 33a - Acquired Rights Specific to Nurses Responsible for General Care (Romanian Nurses)</p>	<p>Amended article 33a lists two additional qualifications that, together with the required period of experience practising as a nurse (see point below), mean that nurses trained in Romania with these qualifications will have acquired rights.</p> <p>Amended article 33a changes the period of experience required in addition to formal qualifications from 5 consecutive years of the last 7 years, to 3 consecutive years of the last 5 years.</p>



<b>Dentists</b>	
Amendments to Article 34 – Basic Dental Training	In paragraph 2, the first sub-paragraph revision includes a requirement that formal qualifications may be expressed through the equivalent ECTS credits.
	In paragraph 2, the first sub-paragraph also introduces a further requirement that the 5 years of study must comprise at least 5,000 hours of full-time theoretical and practical training.
Amendments to Article 35 – Specialist Dental Training	Re-wording of paragraph 1 removes the reference to 5 years of training and states instead ‘basic dental training referred to in article 34’.
	In paragraph 2, second sub-paragraph, ‘it’ is amended to ‘they’.
Amendments to Article 37 - Acquired Rights for Dental Practitioners	Article 37(3) sets out that the acquired rights for automatic recognition under article 23 will apply to all dental courses that are listed in Annex V and have been commenced before 18 January 2016.
	Article 37(4) takes account of dentists who qualified in Spain during the period specified.
<b>Midwives</b>	
Amendments to Article 40 – the Training of Midwives	Paragraph 2(a), entry requirement for midwifery training is increased from 10 years of general education to 12.
	Paragraph 3(a), ‘adequate knowledge’ is replaced by ‘detailed knowledge’.
	Paragraph 3(c), ‘detailed knowledge’ is replaced by ‘adequate knowledge’.
Amendments to Article 41 – Procedures for the Recognition of Evidence of Formal Qualifications as a Midwife (Midwives Minimum Training)	Changes to the minimum requirements for automatic recognition of midwifery qualifications between Member States.
	In paragraph 1(a): added equivalent ECTS credits accepted and consisting of at least 4,600 hours of theoretical and practical training; Change from two years professional practice to one third of the minimum duration representing clinical training.
	In paragraph 1(b) and 1(c): the revision includes a requirement that formal qualifications may be expressed through the equivalent ECTS credits; the course duration must be at least 3,600 and 3,000 hours respectively.

Amendments to Article 43 – Acquired Rights Specific to Midwives	Paragraph 1a. is inserted: anyone who started training to be a midwife before 18 January 2016 shall be recognised even if they have only 10 years of general education.
	Paragraph 3 deleted (restriction on acquired rights for Polish midwives).
	Paragraph 4(b)(ii) adds a further upgrading programme for the training of Polish nurses which broadens the scope for the qualifications that are automatically recognised.
<b>Pharmacists</b>	
Amendments to Article 44 – Training as a Pharmacist	Paragraph 2, the introduction adds requirement that formal qualifications may be expressed through the equivalent ECTS credits.
	Paragraph 2 sub-paragraph (b), the following is added: 'during or at the end of the theoretical and practical training'.
Amendments to Article 45 – Pursuit of the Professional Activities of a Pharmacist	Changes the wording of paragraph 2(e) and (f), in particular:  in (e), the words “distribution and dispensing” and “of the required quality” are added;  in (f), “dispensing” replaces “supply” and “of the required quality” is added.
	Paragraph 2(g) is amended and adds a requirement to provide information on the appropriate use of medicinal products.
	In paragraph 2, new sub-paragraphs (h), (i) and (j) are inserted. These require that qualified pharmacists are allowed to access and pursue the following additional activities:  - reporting of adverse reactions to pharmaceutical products to the Competent Authorities;  - personalised support for patients who administer their medication;  - contribution to local or national public health campaigns.