Department for Business Innovation & Skills

TRANSPOSITION OF THE REVISED MUTUAL RECOGNITION OF PROFESSIONAL QUALIFICATIONS DIRECTIVE 2005/36/EC

CONSULTATION RESPONSE FORM

14 AUGUST 2014

Annex V: Consultation on the transposition of the revised Mutual Recognition of Professional Qualifications Directive (2005/36/EC) response form

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The Department may, in accordance with the Code of Practice on Access to Government Information, make available, on public request, individual responses.

The closing date for this consultation is 06/11/2014

Please return completed forms to:

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We would like respondents to tick a box from a list of options that best describes them as a respondent. This allows views to be presented by group type.

	Business representative organisation/trade body
	Central government
	Charity or social enterprise
	Individual
	Large business (over 250 staff)
	Legal representative
	Local Government
	Medium business (50 to 250 staff)
	Micro business (up to 9 staff)
	Small business (10 to 49 staff)
X	Competent Authority
	Trade union or staff association
	Other (please describe)

General:

Question 1: Do you agree with our proposal to revoke and replace the current 2007 Regulations rather than amend them?

Comments:

This seems to be a sensible approach to us. Having both Directives in one piece of legislation should make the provisions easier to understand and apply.

European Professional Card (article 4a – 4d)

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As mentioned previously, the specifics of implementation are difficult to address at this stage as we are awaiting the adoption of an implementing act for the EPC. With this in mind, we have the following questions:

Question 2: Do you have any suggestions for professions that should be included in the EPC?

Comments:

In our view the EPC is not suitable for pharmacists or pharmacy technicians. It should only be introduced for those professions where an 'added value' has been demonstrated. It should not be imposed on member state competent authorities where systems already exist to inform patients and the public via web based registers of individuals who are not only appropriately qualified but also fit to practise. Making it possible for employers and members of the public to check the validity of an issued EPC in circumstances where the holder has only benefited from recognition and has not yet been granted access to the profession has the potential to lead to confusion and seriously undermine the safety of patients and the public.

Risk of confusion is further increased in automatic recognition temporary and occasional service provision cases where an EPC issued by the home member state will not only mean that the pharmacist has a qualification that has been recognised but also grants them access to pursue the pharmacy profession in the UK and hence automatic registration with us and the Pharmaceutical Society of Northern Ireland.

Question 3: Within the scope of article 4a.7 of the Directive relating to the power to adopt an implementing act, can you suggest any issues that we should be conscious of with regards to the EPC?

Comments:

One of our major issues relates to the fact that the process in the Internal Market Information (IMI) system supporting the EPC relies on the professional choosing from the outset

- **whether they wish to apply for establishment or temporary or occasional service provision and**
- **their route to recognition in the host member state.**

The professional would then be required to upload documents to support their chosen form of service provision and recognition which the home member state is to verify and authenticate. The receipt and validation, by the home member state, of information and documents submitted by the professional and their transmission to the host member state is to replace the application for 'recognition' of professional qualifications stage of our application process.

The recognition stage of our current application process is where we check all documents and information concerning the professional's qualifications and work experience.

Under the EPC process we will only be able to check whether the route to the register selected by the professional and confirmed by the home member state is correct in applications for establishment and in those temporary and occasional service provision applications where the professional and home member state have indicated that a check of qualifications is permissible prior to the first provision of services because the pharmacist's qualification falls under the General Systems.

In establishment cases if the home member states disagrees with a professional' s selected route, the home member state, as we understand the process, can only advise the professional that they have chosen the wrong route but if the professional insists and the pre-set time limit is reached the EPC information is transmitted to the host member state.

In our view where the home member determines that the professional has made a mistake in selecting their route to recognition, the EPC should not be transmitted to the host member state. The matter should be resolved between the professional and the home member state via the home member state's resolution and national appeal procedures. We have had one appeal where the registrar's decision to require compensation measures in the case of an applicant that we had identified as a General Systems case was upheld. Throughout the appeal process the professional continued to insist that they had automatic rights to recognition. Defending that appeal, instructing solicitors and counsel cost the former regulator thousands of pounds and although a costs award was made against the individual this remains outstanding.

There should be a duty on the home member states to cooperate with host member states and not transmit the EPC to the host member state where the professional has either:

- **selected the wrong route to recognition and on advice not amended this**
- **no rights to recognition under the Directive because of nationality or**
- **no rights to recognition under the Directive but falls under treaty rights and ECJ**

We also remain concerned as to whether a home member state can correctly determine whether or not a non-EEA national has a Community right in a host member state and whether that should always remain the role of the host member state to determine.

Furthermore we will be unable to check the EPC prior to it being issued by the home member state in all cases where the professional has indicated and the home member state has confirmed that they do have automatic rights to recognition and wish to provide temporary and occasional services here.

We believe it is for us to decide in cases of temporary and occasional services whether the professional has rights to automatic recognition of their qualification or work experience or if they should follow the General Systems route to our register. This decision should not be made solely by the professional and the home member state especially as temporary and occasional EPCs have a different status in that they represent both recognition of professional qualifications and entitlement to practise as opposed to recognition of qualifications alone. It is very important that the Implementing Act provides a role for the host member state Competent Authority to determine the route

to recognition in these circumstances. In the interests of patient safety, where we determine that the professional's qualification falls under the General Systems, and substantial differences are identified following the comparative assessment of their qualifications and experience, we can require them to pass an aptitude test before being permitted to provide temporary services for the first time. Additionally the alert mechanism should be linked with temporary and occasional EPCs to minimise the risk to patients of a service provider continuing to provide services here when prohibited from practising in their home member state.

At present we have no pharmacy professionals on Parts 4 or 5 of our register providing temporary and occasional pharmacy services here. However as the EC's main purpose is to simplify and speed up free movement with the help of the EPC, this will undoubtedly change. Increasing the use of temporary and occasional registration will have public protection implications as pharmacy professionals under these provisions will not be required to:

- **have in place appropriate cover under an indemnity arrangement;**
- **comply with our CPD, or any future assurance of continuing fitness to practise requirements;**
- **comply with our future language controls or**
- **pay registration or renewal fees.**

An additional concern relates to the documents that a professional would need to upload into the on-line IMI system for the EPC and especially whether we will be able to require foreign language documents to be accompanied by official translations produced by a professional translator.

Under our current application procedures we require official translations of all documents that are not in English. This enables us to cross check all relevant details across all documents submitted by the applicant to reduce the risk of a fraudulent application being passed to registration. Basing decisions on ordinary translations for the EPC runs the risk of undermining our scrutiny processes which are applied robustly and consistently across all applications we receive, irrespective of whether UK qualified/international or European.

In General Systems cases, official translations of academic transcripts, curricula and professional experience ensures that an accurate comparative assessment can be made of the applicant's qualifications and professional experience (wherever obtained) against our national qualification requirements. Ordinary translations or in built machine-translations provided in IMI would not provide the level of detail and accuracy we need.

In conclusion we are of the view that we should not be required to process EPC applications for either General Systems or temporary and occasional service provision unless the Implementing Act enables us to receive official translations for General Systems cases and provides a clear role for the host member state to challenge an issued EPC or determine the route to registration in the case of temporary and occasional service providers. If the pharmacist profession was included in the first phase of EPC implementation, we would support a derogation that would allow us not to use the EPC process in these situations.

Question 4: *Do Competent Authorities expect the EPC to deliver any cost savings from the transfer of responsibility for checking qualifications to home Member States? Please provide any detail possible on the expected cost implications of the EPC for your authority.*

Comments:

We do appreciate that the IMI system supporting the EPC process will continue to develop and improve however we do not see there being any cost savings. On the contrary we see that our administrative costs are likely to increase not least because of the need to continue to provide the current application process in addition to the EPC. Other reasons for costs rising include the following:

- **On receipt of an EPC file we would still validate and authenticate documents in the file and anticipate that we would need to liaise with both the professional and the home member states to do this. This will ensure that all applications to our register whether via the current route or the EPC route would be scrutinised to the same degree of robustness and consistency in the interests of patient safety and the maintenance of public confidence in our regulatory role. Where justified doubts persisted we would refuse to issue an EPC rather than run the risk of the IMI system doing so automatically when the time limit had been reached thereby granting tacit recognition.**

- **We are therefore more likely to reject applications when for example additional information needed to clarify the professional's route to recognition of qualifications till remains outstanding. In the current application procedure we would remind the professional or home Competent Authority to provide the required information and place the application on hold until this was received. Rather than speeding up the process the threat of tacit recognition under the EPC could have the opposite effect. It could also lead to increased administrative burden and costs associated with any appeals.**

- **As we understand the process even where the home member state has concerns about the authenticity or validity of documents uploaded into the IMI system by the professional or where the professional has selected the wrong route to recognition, or may not even have any Directive rights, the EPC file will still be transmitted to the host member state when the time limit for processing by the home member state has been reached. This means that the administrative burden to resolve such issues will fall onto the host member.**

- **All our application procedures require applicants to pay the requisite fee up front. If payment is not received we do not process the application. Therefore the matter of not being able to regard non-payment of EPC processing fees as a missing document by host member state jurisdictions where payment for processing applications is set by administrative and regulatory rules must be resolved. This is of particular concern in General Systems cases where we employ expert academic and professional assessors to assess applications against our national**

qualification requirements for registration. The role of the assessors is to assess all the information submitted and where substantial differences are identified they also recommend the compensation measure which the professional must successfully complete before they can be regarded as being appropriately qualified. We pay assessors for this work. We should not be required to go to the expense of carrying out such comparative assessment and providing the professional with a reasoned decision within the time frames permitted in the EPC route if there is any risk that the professional will not submit payment. We hope to continue to work with the EC, DH and BIS to resolve this issue.

Partial Access (Article 4f):

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Question 5: Bearing in mind the requirements for partial access set out in the Directive (article 4f.1), which professions do you consider eligible for partial access and why?

Comments:

We do not believe that the proposals to implement partial access should apply to pharmacists even if brought under Article 4(f) in the Directive by virtue of Article 10(b) and 10(g) of Chapter I of Title III for the following reasons:

- **In our view partial access undermines the whole principle of minimum training requirements (MTRs) listed in Article 44 of the Directive on which mutual automatic recognition for pharmacists is based. Mutual automatic recognition based on compliance with MTRs was first introduced for pharmacists in 1985. Since that time all member states, on accession, have been required to ensure that only pharmacist qualifications compliant with the Directive MTRs are awarded. These compliant qualifications must also give holders access to at least all of the activities listed in Article 45 of the Directive.**

- **Partial access also undermines the scope of the Directive as set out in Article 2 (2) whereby even member state nationals who have completed qualifications outside the EEA should only have their qualifications recognised to practise a regulated profession by a member state if that recognition is in accordance with the MTRs for that profession.**

- **By definition partial access should only be applicable where a compensation measure would be so great as to amount to a requirement for the individual to complete the full programme of education and training. If the difference in an applicant's education, training and professional experience when compared to the national requirements for registration were so great as to require such a compensation measure then permitting that individual to access any role usually undertaken by a pharmacist here would present a real risk to patient safety. Partial access would seriously undermine our statutory function of protecting patient safety.**

- **In the case of European qualified pharmacy technicians if the comparison of the applicant's qualifications with the national requirements identified substantial differences requiring the individual to complete a number of modules comprising the UK vocational pharmacy technician qualifications then this could be achieved within the Directive General Systems provisions that permit a period of adaptation training with assessments without the need to apply the partial access provisions.**

- **Instead of introducing partial access for pharmacy professionals it would be better, in the interests of patient safety, to maximise use of the compensation provisions. A period of adaptation (with assessments) can last as long as 3 years and we would wish to explore the potential of using a derogation to be able to require not only an adaptation period but also aptitude test(s) where the level of qualification**

is considerably lower than level (e) as defined in article 11. (see also response to question:11)

Question 6: Do you think that we should require applicants who wish to access a profession on a partial basis to do so using the title for that profession in English rather than the professional title of their own state? Is the answer different in relation to different professions?

Comments:

Please see answer to question 5 above – we do not support partial access for pharmacists or pharmacy technicians on the basis that this will have serious implications for patient safety. We would also urge DH and BIS to seek clarification as to whether these provisions should apply to the sectoral professions irrespective of whether recognition falls to be considered under Article 10 of Chapter I or under the automatic routes provided by Chapter IIIa or III of Title III.

Question 7: Are Competent Authorities able to provide any estimate of the cost of addressing an individual partial access case as well as any costs associated with changes (such as IT systems) to their registers to accommodate partial access?

Comments:

We are unable to provide any estimate of costs at this stage.

Temporary service of provisions (articles 7, 8):

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Question 8: Do the new requirements for temporary provision require clarification?

Comments:

The requirement in relation to the language declaration requires clarification. It is unclear to us whether this is to be a self-declaration made by the professional themselves, or a declaration as to the professional's language ability made by a language course provider, university or employer.
We would also appreciate a clearer definition of what constitutes 'establishment'. When temporary and occasional service provision was first introduced for pharmacists we were advised by the EC that a person was lawfully established in a home member state merely as a consequence of holding a pharmacist's qualification that would entitle them to practise without the need to demonstrate any actual professional practice. It remains our view that to be legally and professionally established in a home member state there must be evidence of profession practice in that home state.

Question 9: In relation to the option to require a language declaration in relation to professions with safety implication, which professions do you think fall within this description?

Comments:

In our view the professions which fall within this description include pharmacists and pharmacy technicians.

Question 10: Do any Competent Authorities anticipate additional costs incurred from the temporary service provision amendments?

Comments:

An increase in numbers of pharmacy professionals seeking temporary and occasional registration which the EPC would facilitate could increase the financial burden of regulation on those who hold full registration.

Conditions for recognition (article 13):

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Question 11: Are the conditions for recognition sufficiently clear?

Comments:

With the changes to Article 13 and in particular article 13 (4) – it would appear that under the General Systems route for pharmacists for example we would need to consider applicants who only have a qualification in pharmacy defined under Article 11(b) ie a secondary course when we require a level 11(e) qualification ie a post secondary course of at least 4 years in duration. Again in our view this undermines patient safety and would appear to have been introduced to fall in line with partial access provisions where this it to be an alternative option in circumstances where a compensation measure of greater than 3 years is likely to be required.

A further concern here is that this has the potential for General Systems applications to blur the distinction between professions such a pharmacy technician, prescriptionist (in the Scandinavian countries) and pharmacist.

Currently for example we do not permit a holder of a non-EEA pharmacy qualification of less than 3 years duration to complete our international registration route which consists of a one year Overseas Pharmacists' Assessment Programme + 12 months pre-registration training and the registration assessment. This is on the basis that even after completing the 2 year qualifying requirements they would still not have a qualification which met the Directive minimum training requirements as regards duration and we would be in breach of Article 2(2). We are aware that other Member States have recognised shorter programmes from non-EEA countries and permitted holders of such qualifications to practise as pharmacists.

This new provision could make such recognition more widespread. Assuming that such individuals had worked in the recognising member state for 3 years, we would not consider that they could benefit from Article 10(g) because the original recognition had not been in accordance with Article 2(2). However having obtained recognition of a short qualification and been permitted to practise as a pharmacist (even if perhaps there had been little or no practise in the recognising member state) we would still be required to consider the application under EU Treaty requirements and ECJ jurisprudence of Vlassopoulou and Hocsman.

The changes have the potential to increase the number of applicants that we may receive seeking recognition under either the General Systems or EC Treaty rights with consequential increase in numbers undertaking compensation measures or seeking to appeal decisions.

Compensation measures (article 14):

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Question 12: Although the applicant has the right to choose, Members States' can stipulate, by way of derogation, an adaptation period or aptitude test. Do you think there is a case, in relation to a profession, for expanding the category of cases where we may stipulate either an aptitude period or adaptation test as set out in Article 14.3? If so, please provide reasons for this.

Comments:

We have a derogation in existing implementing legislation removing an EEA pharmacist's right to choose which we would like to maintain.

Where a compensation measure is required under the General Systems we currently require EEA pharmacists to successfully complete an adaptation period with assessments. This is because at present we are only considering an applicant that may potentially have a qualification that is only one level below the level we currently require, that is a qualification defined by Article 11(d) as opposed to the qualification defined by Article 11(e). The period of adaptation with assessments provides assurance that the applicant has acquired the knowledge missing by directed self-learning and is able to demonstrate that they can apply this in practice under the supervision of a registered pharmacist.

In the revised Directive where we will be required to consider qualifications that are much lower, for example a qualification at a level defined by Article 11(c), we would wish to derogate and specify an aptitude test rather than an adaptation period with assessment. This is because in these cases a more formal assessment of the knowledge element that we have identified as missing would be required to provide assurance that an applicant has indeed acquired the depth of knowledge crucial for safe and effective practice.

We would be interested to explore whether it would be possible to have different derogations. For example we would wish to continue with the current derogation and require an adaptation period with assessment if the qualification was only one level lower than that required by us but change the derogation to an aptitude test when the qualification was more than one level lower or to even be permitted to require both a period of adaptation training together with an aptitude test if that was deemed to be proportionate on a case by case basis.

Additionally we would wish to apply for a derogation for European qualified pharmacy technicians and be able to stipulate a period of adaption training with assessments. The pharmacy technician qualification in the UK is a vocational qualification and as such we do not consider that an aptitude test is an appropriate compensation measure.

Question 13: Does applying a compensation measure raise the administrative costs of processing an application?

Comments:

Yes there is an increase in total cost both to the professional and to us as the host competent authority. There is no increase in costs associated with processing the actual application to the stage of decision on compensation measures as this would be the same whether a compensation measure was ultimately required or not.
However if a compensation measure is imposed the applicant would incur additional costs associated with successfully completing the compensation measure.

We also incur additional costs associated with administering the compensation measure, reassessing the application once compensation measure completed and covering our costs should the applicant decide to appeal the decision.

Recognition of professional traineeship (article 55a)

Page 19

Question 14: What limits to the duration of professional traineeships should be set, if any, in relation to a relevant profession?

Comments:

We currently permit a period of 13 weeks' of professional traineeship to be undertaken outside the UK in another European member state. This can only be undertaken during the first 26 weeks of the 52 week period of pre-registration training that forms part of the UK pharmacists' qualification (see response below).

We do not believe that this should be increased.

We do not permit or recognise professional traineeship undertaken outside the EEA for the purposes of completing the UK pharmacists' qualification.

Question 15: Are there any current guidelines on organisation and recognition of professional traineeships?

Comments:

Our guidelines on professional traineeships are set out in Procedures for the Initial Education and Training of Pharmacists and Pharmacy Technicians in Great Britain and Northern Ireland available on our website. Pharmacist pre-registration training is managed by a pharmacist tutor at an accredited training site. Further details on tutor and training site requirements are also available on our website.

The pharmacist pre-registration training scheme forms part of the education and training leading to initial registration as a pharmacist in Great Britain. It usually takes place after successful completion of the 4-year Masters' in pharmacy degree and comprises:

- **a 52 week period of professional training, at the end of which pre-registration trainee pharmacists must have been signed off by their tutor(s) as having met the GPhC's Pre-registration Performance standards; and**
- **the registration assessment which must be passed.**

Our procedures permit a 13 week block of training to be undertaken outside the UK in another European member state in the first 26 weeks of pre-registration training. The request to do so must be submitted at the outset as part of the 52 week pre-registration training plan.

Automatic recognition on the basis of common training principles (articles 49a and 49b):

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These principles are subject to delegated acts adopted by the Commission. Therefore we are interested in your views in general terms only at this stage.

Question 16: Is the provision for setting up common training principles/frameworks of interest to your profession?

Comments:

At this stage we are unclear about the exact level of interest. We are however aware that there may be some interest from other member states mainly because prior to accession specialist qualifications in hospital, community and industrial pharmacy were available in many East European countries. There is also some interest from European pharmacist professional organisations such as the European Association of Hospital Pharmacists http://www.eahp.eu/press-room/european-parliament-improves-professional-qualification-rules

As part of our regulatory role we work with stakeholders to set learning outcomes and standards for the initial education and training of pharmacists and pharmacy technicians and accredit and approve providers of courses that lead to registration. Likewise we also set standards for courses leading to annotation to the register e.g. independent prescribing course for pharmacists and accredit courses that lead to this annotation. If a specialist pharmacist qualification were being developed under common training principles that could lead to specialist registration or annotation to the register we would want to be involved in that process. In the interests of patient safety such courses would need to be accredited by us if provided by UK higher education institutions to ensure their quality.

Question 17: Do you consider your profession to be outside the scope of a CTF or CTT and why?

Comments:

We believe that the profession of pharmacist is possibly within the scope of common training frameworks with regards to specialist pharmacist qualifications by virtue of Article 49a(7).

Question 18: Do Competent Authorities expect common frameworks and tests to reduce administrative costs in processing PQD applications?

Comments:

We cannot comment as there are currently no specialist pharmacist qualifications covered by the Directive.

Access to information (articles 50.3, 57, 57a):

Page 20

Question 19: Are your procedures already available online?

☐ Yes ☒ No ☐ Not sure

Comments:

Information on how to make an application for recognition and registration, and the documents and the format in which these are to be provided, is available on our website. However the ability for individuals to make an on-line application to us for both recognition and registration is not currently possible. We are in the process of upgrading the IT systems that support our regulatory functions and registers. We hope to complete the first phase by Spring 2015 with a view to move to on-line self-serve application processing in the next phase of development.

Question 20: Do you accept electronic payments?

☐ Yes ☒ No ☐ Not sure

Comments:

We process payments for all applications via a secure on-line payment facility once the applicant has provided us with details of the credit or debit card they wish to use for payment purposes. Applicants for recognition and registration cannot make electronic payment themselves.

Question 21: Is your Competent Authority already linked in to the PSC?

☐ Yes ☐ No ☒ Not sure

Comments:

We don't think we have a presence on the PSC set up by Directive 2006/123/EC because pharmacy services are excluded from the services Directive. However we do have a presence on the UK National Contact Point for professional qualifications and also on the EC's Europa website.

Question 22: Are Competent Authorities able to provide any information about the expected costs and time taken to make available information through the Points of Single Contact?

Comments:

To ensure that information available to European qualified pharmacy professionals was always accurate and up to date we would rather the PSC provided links to our website rather than have separate information available on their website. We cannot provide an estimate of costs or time taken to up date the PSC. Costs and time taken would be dependent on how much detail would be available on the PSC.

Question 23: Do any Competent Authorities expect substantive costs to arise from providing electronic application processes? Could you please specify expected costs?

Comments:

Costs of providing electronic application processes have been included in the development costs of our new IT systems. Until the Implementing Act for the EPC has been made it is unclear what the additional costs of processing applications via the EPC route would be.

Question 24: Do Competent Authorities who have switched to online application systems have any information on the impact this may have had on number of applications?

Comments:

We have not yet switched to online applications and therefore do not know what impact this may have on numbers of applications.

Exchange of Information (article 56)

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Question 25: Are you aware of IMI?

☒ Yes ☐ No ☐ Not sure

Comments:

Question 26: Are you registered with IMI?

☒ Yes ☐ No ☐ Not sure

Comments:

Question 27: If you are already registered on IMI:

a. do you find the system easy to use?
b. do you find the information exchanged useful?

a.	☐ Yes	☒ No	☐ Not sure
b.	☒ Yes	☐ No	☐ Not sure

Comments:

We do not find the IMI system easy to use. This is because the system is not intuitive and as we use it so infrequently we have to spend time re-learning how to use it each time.

Question 28: Do you consider you should be designated as a coordinator? Please provide reasons.

Comments:

In the UK there are 2 Competent Authorities that regulate pharmacists. The General Pharmaceutical Council (GPhC) and the Pharmaceutical Society of Northern Ireland (PSNI). The GPhC also regulates pharmacy technicians in Great Britain.

Both the GPhC and PSNI are responsible for recognising the qualifications of European qualified pharmacists who apply to register directly with them.

The GPhC works very closely and collaborates with PSNI via an MoU and in the European context more specifically by means of a Service Level Agreement. Under this agreement the GPhC undertakes the processing of General Systems applicants on behalf of PSNI. GPhC assessors complete the comparative assessment of an applicant's qualifications and work experience against the UK requirements for registration and provide a recommendation on compensation measures if these are required on a case by case basis. The applicant is able to complete the compensation measure in Northern Ireland and apply to register with PSNI once this has been successfully completed.

In relation to the alert mechanism both the GPhC and PSNI have their own fitness to practise processes and each should be responsible for sending and receiving alerts within the IMI system within the 3 day deadline.

In view of the administrative delay that a co-ordinator would undoubtedly introduce with risks of missing the tight time scales in the alert mechanism and the EPC process it may be more efficient not to appoint a co-ordinator but to permit both the GPhC and PSNI to act as separate Competent Authorities within their own jurisdictions for the UK.

Question 29: Are affected Competent Authorities able to provide more information on how many additional staff may need to use IMI for the alert mechanism and the potential on-going costs of using the system?

Comments:

Currently only 4 GPhC employees are named IMI users. When the IMI system is expanded to cover both the alert mechanism and the EPC process we would expect many more employees needing to be trained to use the system.

In relation to the alert mechanism we would expect that 5 additional members of staff would need to be trained from within the fitness to practise teams.

In relation to application processing via the EPC route (acting as both home and host member state) we expect that as a minimum a further 6 members of staff would also need to be trained to use the IMI system.

A further 10 individuals would also need access to IMI and receive training. This is to cover members of staff in our customer contact centre who deal with enquiries but this may only need to be in 'view only' mode.

We therefore estimate that at least 21 additional GPhC employees may need to be trained to use the IMI system.

We see training as an ongoing requirement as IMI develops and new staff join the organisation.

Alert Mechanism (article 56a):

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As with the EPC, the specifics of implementation are difficult to address at this stage as we are awaiting the adoption of an implementing act for the Alert Mechanism. With this in mind, we have the following questions:

Question 30: Within the scope of the implementing act (article 56a.8), can you suggest any issues that we should be conscious of with regards to the Alert Mechanism including:
- Eligible authorities or coordinators
- Procedures on treatment of alerts
- Security of processing alerts?

Comments:

We are supportive of the Alert mechanism and believe that it should result in better information sharing between competent authorities.

Eligible authorities or coordinators
Both the GPhC and PSNI have their own fitness to practise processes and each should be responsible for sending and receiving alerts within the IMI system within the 3 day deadline.

In view of the administrative delay that a co-ordinator would undoubtedly introduce with risks of missing the tight time scales in the alert mechanism it may be more efficient not to appoint a co-ordinator but to permit both the GPhC and PSNI to act as separate Competent Authorities within their own jurisdictions for the UK.

Content of alerts
In relation to identifying the professional concerned we believe it is important to have the option of entering as much information as possible to identify the individual. For example under name; we should be able to include the individual's family name at birth and change of name on marriage.

It would also be helpful to have clarity about the types of alerts that are to be sent, whether these will be pre-set within the IMI system and whether we will be consulted on what these should be. We understand that fitness to practise decisions where a professional has been removed from practice, suspended or had conditions imposed on their practice or where removal was due to fraud, would need to be communicated but it is unclear whether other removals such as voluntary removal, administrative removal for non-compliance with our CPD requirements or removal for non- payment of renewal fees would also need to be notified.

Withdrawal and closure of alerts
We would like clarification as to the difference between an alert that is withdrawn and an alert that is closed.

Updating of alerts
No time limit is specified for updating alerts. Is this again to be 3 days from the date of any relevant decision and would updates also be triggered in situations where the

professional has changed their name following marriage, deed poll etc. and how will this be linked to the original alert?

Right of appeal

It would be helpful to clarify whether the right of appeal in Article 56a(6) of the revised Directive is an appeal against the decision to issue the alert as opposed to an appeal against the decision contained within the alert. Appeal mechanisms already exist against fitness to practise decisions that would be contained within the alert and we therefore see this appeal under the Directive as an appeal to issue the alert on the grounds that it identified the wrong pharmacist or was in any other way inaccurate. Confirmation of this would be helpful.

Transparency initiative (article 59):

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Question 31: Do you have any views on the most effective exercise of the transparency process?

Comments:

The information provided for the EC database replicates information which is already freely available on either our website or that of the Professional Standards Authority. Information on our national websites is regularly updated. It is unclear how often information on the EC database will be reviewed. This may result in member state competent authorities accessing potentially inaccurate and out of date information. It would be useful for the database to include a date of completion and a prominent statement advising that users should check the national competent authority's website to confirm whether or not legislation or procedures on a particular issue had changed since then.

Question 32: Do you know of any Chartered Bodies that should be either removed or added from Annex I? Please give reasons for your answer.

Comments:

This is not applicable to the GPhC

Question 33: Do you know of any regulated professions that should either be removed or added from Schedule I? (http://www.legislation.gov.uk/uksi/2007/2781/schedule/1/made) Please give reasons for your answer

Comments:

This is not applicable to the GPhC

Question 34: Has your Competent Authority updated the information on the database (A request to complete the 'Proportionality' tab was sent on 18 July 2014)?

Comments:

Yes the proportionality tab has been completed.

Under Article 59 there is a requirement to notify to the Commission the list (and justification) of the professions for which a prior check of qualifications is necessary under Article 7(4). Article 7(4) permits a prior check for regulated professions that have public health and safety implications and that do not benefit from automatic recognition. For the GPhC this is all applications received from pharmacy technicians and applications from pharmacists under Article 10(b) and 10(g). Can this please be notified to the Commission.

The EC database does not permit us to state the accurate position for General System pharmacists in relation to Article 7(4) where we believe a prior check of qualifications is justified for public health and safety reasons. We are grateful to BIS for liaising with the EC to correct this.

Do you have any other comments that might aid the consultation process as a whole?

Please use this space for any general comments that you may have, comments on the layout of this consultation would also be welcomed.

Thank you for your views on this consultation.

Thank you for taking the time to let us have your views. We do not intend to acknowledge receipt of individual responses unless you tick the box below.

Please acknowledge this reply ☒

At BIS we carry out our research on many different topics and consultations. As your views are valuable to us, would it be okay if we were to contact you again from time to time either for research or to send through consultation documents?

☒ Yes ☐ No

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