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Sent by email

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To whom it may concern,

Response from the General Pharmaceutical Council to the Department of Health's call for evidence: EU balance of competence review.

I am pleased to attach the General Pharmaceutical's response to the Department of Health's call for evidence: EU balance of competence review.

Yours faithfully



HUGH SIMPSON
Director of Policy and Communications
General Pharmaceutical Council

Introduction

The General Pharmaceutical Council is the regulatory body for pharmacists, pharmacy technicians and registered pharmacies in England, Scotland and Wales. We are very pleased to be able to respond to the Department of Health's call for evidence: EU balance of competence review.

In the following, we will briefly outline our role and functions and then address the areas where the EU has an impact on our regulatory remit.

Our role and functions

We are the newest of the nine statutory health professional regulators in the UK. The Pharmacy Order 2010, endorsed by both the UK and Scottish Parliaments, set out the regulatory powers of the General Pharmaceutical Council in Great Britain and brought regulation of the pharmacy professions in Great Britain into line with other health professions, with a statutory regulatory body quite separate from the professional leadership body. The Pharmaceutical Society of Northern Ireland retains both roles in Northern Ireland.

Consistent with the other health professional regulators our legislation makes explicit that our purpose is that of patient protection. Specifically, the Pharmacy Order sets out our role as being:

"...to protect, promote and maintain the health, safety and well-being of members of the public, and in particular of those members of the public who use or need the services of registrants, or the services provided at a registered pharmacy, by ensuring that registrants, and those persons carrying on a retail pharmacy business at a registered pharmacy, adhere to such standards as the Council considers necessary for the safe and effective practice of pharmacy."

Our principal functions are set out in Article 4 (3) of the Pharmacy Order 2010. These cover:

- Approving qualifications for pharmacists and pharmacy technicians and accrediting education and training providers;
- Maintaining the register of pharmacists, pharmacy technicians and pharmacy premises;
- Setting standards for conduct, ethics, proficiency, education and training, and continuing professional development (CPD);

- Establishing and promoting standards for the safe and effective practice of pharmacy at registered pharmacies;
- Establishing fitness to practise requirements, monitoring pharmacy professionals' fitness to practise and dealing fairly and proportionately with complaints and concerns.

We are unique amongst the UK health professional regulators as we also have a statutory role in relation to 'system' regulation that consists of the regulation of registered pharmacies from which pharmacy services are provided.

Our response is based on comments made previously to European consultations and calls for evidence.

Below we have considered;

1. Current challenges relating to implementation of European Directives.
2. Future opportunities.
3. Future challenges.

1. Current challenges relating to implementation of European Directives

Section 13 – Implications of free movement of persons: healthcare professionals – The Recognition of Professional Qualifications (RPQ) Directive.

Automatic recognition

Regulators must efficiently manage the registration process in accordance with domestic and EC law and assure themselves that the professionals they register are fit to practise and will not put patient safety at risk.

We have considerable experience with high levels of mobility both from Europe and internationally. The numbers of European qualified pharmacists registered from 2001 to 2012 under the automatic route to recognition of qualifications provided by the Recognition of Professional Qualifications (RPQ) Directive is provided in Annex 1.

From a patient safety perspective, automatic recognition based on diploma compliance with the minimum training requirements takes no account of whether an applicant has maintained their professional competence since qualification or of the steps they have taken to keep their knowledge and skills up-to-date.

The concept that primary qualifications have decreasing value over time as a measure of evidence for initial registration when not associated with relevant work experience is an accepted principle and also critical in assuring public confidence. This is one of the principles which underpin the move to require continuing professional development.

We remain concerned that an EU national with a qualification listed in the Annex and started after 1 October 1987 reference date and awarded in 1992 for example, which complies with the minimum training requirements of Article 44 is entitled to automatic recognition of that qualification and registration (provided they satisfy health and character requirements) even though they may have not practised at all in their home or any other member state since qualification. In the interests of patient safety such individuals should also be required to satisfy the national competent authority's 'return to practice' requirements that includes providing evidence of any completed continuing professional development activities since qualification before being granted registration and a licence to practise. This would align with what is required of a UK qualified person who had completed a degree in 1992 and had not practised as a pharmacist since.

Language

From a patient perspective, communication is key to building trust in the patient-practitioner relationship. It also goes without saying that clinical information and advice must be communicated clearly and accurately to patients. Robert Francis QC, in his report of the Mid Staffordshire NHS Foundation Trust Public Inquiry included at recommendation 172, a recommendation that *'Government should consider urgently the introduction of a common requirement of proficiency in communication in the English language with patients and other persons providing healthcare to the standard required for a registered medical practitioner to assume professional responsibility for medical treatment of an English-speaking patient'*.

The implementation of the RPQ Directive in our governing legislation prevents us requiring 'exempt persons' (i.e. EEA nationals) from meeting any requirements to demonstrate that they have reached an adequate standard of proficiency in the knowledge and use of English. This provision does not, however, apply to non-EEA Nationals.

We agree that language competency is not a relevant consideration when determining whether an applicant holds a qualification which entitles them to mutual automatic recognition; the 'recognition stage' of an application.

Similarly, the standard of an applicant's language competency is not a factor to be considered when comparing an applicant's qualification with the national requirements for

registration under the general system of recognition to ascertain whether compensation measures are required prior to registration.

However, once we are satisfied that the applicant holds a qualification which complies with the requirements of the Directive (or following completion of any compensation measure) an applicant will move to the second stage – the registration stage.

According to Article 53 of the Directive such an applicant would have benefited from the recognition of professional qualifications and *‘shall have knowledge of languages necessary for practising the profession in the host member state’*.

We are therefore firmly of the view that, following recognition but prior to registration, we should be able to require applicants to provide some assurance or evidence of their language competency necessary for safe and effective practice in the UK.

We acknowledge the important role played by employers ensuring that professionals are fit for a particular position but would like to highlight that a significant number of the professionals we regulate carry out work in a self-employed capacity. We believe that a regulator must ensure that all professionals are fit for practice at the point of registration, including their ability to effectively communicate.

We have anecdotal evidence that language competence is an issue for a number of EEA applicants seeking registration with us. We provide information on our website about the importance of having the necessary language skills to communicate and work effectively with patients and colleagues. <http://www.pharmacyregulation.org/registration/registering-pharmacist/eea-qualified-pharmacists>

We have also conducted a limited review of fitness to practise cases between 2008 and early 2011 and identified two cases where our inability to refuse registration on grounds of a lack of English language proficiency posed a risk to patients. These cases are summarised in Annex 2.

Exchanging Fitness to Practise information

With increasing movement of healthcare professionals around Europe, there is clearly an increasing risk that some health practitioners may seek registration in other parts of Europe when they have been erased or suspended from the register or in order to avoid disciplinary action in their home country. We have worked with colleagues as part of the Healthcare Professionals Crossing Borders (HPCB) initiative. HPCB is an informal partnership of professional healthcare regulators from within Europe. HPCB works to ensure that health professionals can effectively take up their rights of free movement whilst emphasising the

importance of regulators being able to share fitness to practise information on both a reactive and proactive basis to establish that these healthcare professionals are fit and safe to practise. We remain concerned that member state regulators do not readily share fitness to practise information with us.

Temporary service providers – Visiting EEA practitioners

We believe that patients have the right, and a clear expectation, to be protected by the national regulatory system regardless of whether the healthcare professional treating them is in the country permanently or temporarily. It is therefore essential that pro-forma registration and the prior authorisation schemes (Article 7.4) are maintained to ensure that healthcare professionals practise in accordance with the professional standards of the host member states and that competent authorities can take fitness to practise action where required.

We view this as essential for protecting patients and maintaining public confidence in the system.

We are concerned that:

- we cannot require prospective temporary service providers to complete the same fitness to practise declarations prior to registration as we require of other applicants for establishment and
- a prospective temporary service provider's right to provide services outside their home member state is determined by the fitness to practise regime in the home member state, not that of the host member state where the services are to be provided.

Section 15: Implications of free movement of services: cross-border healthcare

One of the principal functions of the GPhC as described above is to set and promote standards for the safe and effective practice of pharmacy. Under our Standards of Conduct, Ethics and Performance and the Standards for Registered Pharmacies, the care, well-being and safety of patients is at the heart of professional practice. Pharmacy professionals must make sure that the services they provide are safe and of acceptable quality and to use their professional judgement to act in the best interests of individual patients and the public.

UK legislation and our standards are there to ensure that the right patients receive the right medicines, at the right time, in the right way, with the right information and advice so that medicines can be used safely and in a way that works.

Although the Directive on the application of patients' rights in cross-border healthcare (2011/24/EU) is to be implemented by 25 October 2013 prescriptions given in an EEA member state or Switzerland are already recognised for dispensing in this country.

For patient safety our national legislation¹ stipulates that the following must appear on prescriptions written by UK prescribers

- the patient's name, address and age if under 12,
- the prescriber's signature,
- address of the prescriber,
- particulars that indicate whether the prescriber is a doctor or a dentist etc,
- appropriate date (when the prescription becomes valid).

It is therefore a continuing concern that European prescriptions for dispensing in the UK do not have to include the patient's address¹ or the date of birth.

Pharmacy professionals, when supplying the medicine they have dispensed, check not only the patient's name but also address details as written on the prescription to make sure that the dispensed medicine is supplied to the correct person.

The absence of a date of birth can potentially lead to the pharmacist being unable to readily verify the clinical appropriateness of the prescribed medicine.

From a patient safety perspective, there can be no justification in enabling doctors or dentists from EEA member states to write prescriptions for dispensing in this country that contain less information than is required from UK prescribers.

Additionally pharmacy professionals may encounter difficulties in deciding on the right medicine to dispense because of differences in the names, dosage and forms of the medicine available between member states. Brand A may contain one drug (X) in one member state but may contain a completely different drug (Y or Z) in other countries. In the past this has been the case with the brand Acepril containing either enalapril, captopril and lisinopril depending on the member state in which it is marketed.

Prescribers should be required to prescribe using the generic (rINN) name of the medicinal product. Brand names should only be included where, for reasons of differing bioavailability of the product, profile of release or route of administration, it is important for the patient to continue on the same brand of medicine.

¹ The Human Medicines Regulations 2012

Pharmacy professionals also need to assure themselves that the medical prescription presented to them for dispensing is authentic and that the prescriber is authorised to prescribe in the member state where the prescription is given.

It would assist pharmacy professionals if member states were required to have real-time web-based publicly searchable lists of registered professionals who are authorised to prescribe within their jurisdiction similar to the details provided by the General Medical Council on their website www.gmc-uk.org

It should be noted that in the UK in addition to doctors and dentists a number of supplementary prescribers and appropriately qualified nurses, optometrists and pharmacists can also write prescriptions for patients.

2. Future opportunities

Section 13 – Implications of free movement of persons: healthcare professionals - Proposed amendments to the RPQ Directive

Language

We have been following the proposed amendments to the RPQ Directive with interest and welcome the amendments clarifying that language assessment can take place after recognition of the professional qualification but before access to the profession by or under the supervision of the competent authority for all healthcare professionals.

The proposed alert mechanism

We also welcome the proposed amendments to the RPQ Directive that introduce an alert mechanism in the revised RPQ Directive but consider that it should be extended to all health and social care professions, regardless of whether they have had their qualifications recognised under automatic recognition or general systems. Alerts about all healthcare professionals should be treated with the same urgency as the risk to patient safety is the same.

Additionally any alert mechanism should cover any restriction on a professional's licence to practise. Restrictions short of removal from the register or suspension, such as conditions on a licence or limitations to scope of practice, can indicate serious issues about a professional's practice and these should be communicated to all other competent authorities.

Administrative co-operation

In our experience the implementation of the internal market information (IMI) system has improved administrative co-operation between us and home member state competent authorities.

We welcome the extension of IMI to competent authorities for all healthcare professions, mandatory registration with IMI and the proposed enhanced role for the IMI system in the alert mechanism.

3. Future challenges

Section 2: Medicinal products – Directive 2011/62/EU amending Directive 2001/83/EC (The Falsified Medicines Directive)

As explained above we have the dual role of regulating pharmacy professionals and pharmacies and because of this we have powers to set standards for registered pharmacies.

In the UK medicinal products for human use are divided into prescription only medicines and non-prescription medicines with the non-prescription medicines category further subdivided into medicinal products that can only be purchased from a pharmacy (P medicines) and medicinal products known as General Sale List (GSL) medicines that can be purchased not only from pharmacies but also from non-pharmacy retailers.

A pharmacy must be registered with the GPhC because the supply of Pharmacy (P) medicines and Prescription only Medicines (POMs) is restricted by law to being supplied from registered pharmacies only. There are exemptions from this restriction and it is because of these that the GPhC does not register dispensing doctors' practices or hospital pharmacies that only make supplies that are defined as being made '*in the course of the business of the hospital*'. General Sale List (GSL) medicines on the other hand can be sold from other retail outlets apart from registered pharmacies, such as supermarkets and petrol stations, when the appropriate legal conditions are met.

We have therefore contributed to the recent MHRA consultation on the transposition of the Falsified Medicines Directive into national legislation. This Directive introduces a mandatory EU internet logo that is to be displayed on websites supplying medicinal products (including GSL) medicines on line.

A key consideration for the GPhC will be the impact this has on the current voluntary internet logo which we issue to pharmacies registered with us that sell or supply medicinal products over the internet; whether this should be discontinued following the introduction of the EU logo scheme and how it will be possible, in future, for patients to distinguish easily

between registered pharmacies whose services are fully regulated by the General Pharmaceutical Council), other healthcare providers who may supply medicines over the internet such as doctors providing online consulting, prescribing and supply from hospitals or clinics directly to patients of that doctor where there is no pharmacy involvement and non-healthcare retail organisations who retail GSL medicines over the internet. It is unclear to us how the mandatory logo applied to websites linked to nonpharmacy retailers will benefit patients or promote patient safety.

We support the desire to provide greater assurance to the public when purchasing medicinal products over the internet but remain concerned that the EU logo could give false assurance as it appears that the logo can be copied onto websites that have not been approved by the relevant national competent authority. Additionally in the UK the appearance of the logo may give the public false assurance that they are purchasing medicinal products from regulated pharmacies when this will not always be the case.

Section 13 – Implications of free movement of persons: healthcare professionals - Proposed amendments to the RPQ Directive

The European Professional Card proposed in amendments to the RPQ Directive

We remain sceptical as to whether the proposed European Professional Card will deliver real benefits for the profession and competent authorities.

We consider that the most effective way to ensure the successful implementation of the proposed professional card would be to have a number of pilot projects before being fully introduced to ensure that the proposed system and timelines are safe, robust and realistic.

We consider that responsibility for recognising qualifications under the card should lie exclusively with the host Member State to ensure professionals are appropriately qualified in the country in which they intend to practise. This must be the case irrespective of whether the individual applicant seeks to establish themselves permanently in the host member state or to provide services on a temporary or occasional basis.

We are also firmly of the view that the professional card must only be used for the recognition process and not as a way to confirm the registration status of a professional with patients or employers because of the potential risk of abuse or fraud.

The Directive should not mandate the means by which member states make registration information available to patients and employers. In the UK, healthcare professional regulators make web-based searchable lists of registration and disciplinary information freely available to the public. These are live and updated daily. We consider this is a much more effective and safe way to confirm the status of a professional than checking the authenticity of a 'card' which would be in effect out of date as soon as it is printed.

On average we recognise and register over 400 European qualified pharmacists under the automatic route to recognition each year. This represents approximately 15% of all new registrants each year. We do this well within the 3 month time limit provided by the current Directive (in most cases within 6 weeks from initial enquiry to registration). We would be very concerned if this were to be reduced to two weeks as proposed we would not have the resources to meet such a reduced time limit.

We look forward to seeing the final agreed text of the amended RPQ Directive and to working with both the Department of Health and the Department for Business, Innovation and Skills (BIS) on its implementation.

Section 15: Implications of free movement of services: cross-border healthcare

We have responded to the EC's consultation on measures for improving the recognition of prescriptions issued in another member state that was undertaken under the Directive on the application of patients' rights in cross-border healthcare (2011/24/EU). In our opinion, if a standardised format for these medical prescriptions is to be developed it should comply with the legislative requirements for prescriptions in all of the member states. Measures should also be introduced to reduce the current challenges described in the first part of this response.

Summary

The structure of health care, how it is provided and regulated is a member state competence. EU action in the area of health sometimes fails to take sufficient account of this and mandates solutions such as the European Professional Card and the EU logo for example that when implemented in the UK could potentially undermine the existing safeguards we already have to protect public and patient safety.

Annex 1

Numbers of EEA Applicants Registered – automatic recognition based on diplomas and ‘acquired rights’ 2001 - 2012

MEMBER STATE	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
AUSTRIA	0	0	1	0	3	2	3	0	3	0	1	1
BELGIUM	1	4	1	0	1	2	2	1	1	1	0	0
BULGARIA	nms	nms	nms	nms	nms	nms	3	16	28	16	10	10
CYPRUS	nms	nms	nms	0	0	0	0	0	0	0	0	1
CZECH REPB	nms	nms	nms	2	4	6	7	13	12	6	4	6
DENMARK	4	5	11	6	5	0	6	4	3	1	4	0
ESTONIA	nms	nms	nms		0	3	2	3	4	8	1	1
FINLAND	1	1	1	3	0	2	0	2	0	1	1	0
FRANCE	11	14	12	6	3	5	7	9	7	7	4	6
GERMANY	19	30	36	27	17	23	16	12	20	14	13	8
GREECE	0	2	3	2	5	5	6	2	1	5	11	9
HUNGARY	nms	nms	nms	0	2	11	2	13	17	17	9	10
ICELAND	1	0	0	0	0	2	1	1	1	0	0	0
IRELAND	2	4	8	3	19	20	1	7	4	32	13	14
ITALY	9	24	21	23	24	35	48	40	52	89	67	43
LATVIA	nms	nms	nms	0	1	2	5	3	0	4	5	4
LIECHTENSTEIN	0	0	0	0	0	0	0	0	0	0	0	0
LITHUANIA	nms	nms	nms	1	4	7	5	13	16	26	20	15
LUXEMBURG	0	0	0	0	0	0	0	0	0	0	0	0
MALTA	nms	nms	nms	8	6	8	5	5	1	2	2	2
NETHERLANDS	3	3	2	5	0	2	2	3	1	4	3	1
NORWAY	2	5	0	1	1	0	0	1	0	0	2	1

POLAND	nms	nms	nms	13	124	171	207	118	65	46	32	27
PORTUGAL	1	7	9	4	9	8	15	13	27	16	21	41
ROMANIA	nms	nms	nms	nms	nms	nms	6	26	30	60	64	47
SLOVAKIA	nms	nms	nms	0	0	8	9	10	9	3	6	3
SLOVENIA	nms	nms	nms	0	0	2	1	0	1	0	2	0
SPAIN	159	291	323	158	85	148	107	91	125	132	97	126
SWEDEN	4	13	13	9	14	25	5	6	7	8	2	4
SWITZERLAND	0	1	0	0	1	1	0	1	1	1	0	0
TOTAL	217	404	441	271	328	498	471	413	436	499	394	380

KEY:

nms - Not Member State

Annex 2

Case 1

Mr Y 's case was heard by the Disciplinary Committee on 23 May 2011. The Committee found that there were sustained examples of sloppy and incompetent management of his pharmacy practice. There was a deliberate flouting of his undertaking not to act as his own superintendent pharmacist, and he failed to reach the level in English within the three year time limit allowed by his undertaking. Further, in the knowledge that he had not reached the required level of competence in English, he dishonestly produced a forged certificate to pretend that he had. He denied the subsequent charge in respect of that at trial, but he was convicted. The Committee found the level of dishonesty in attempting to deceive the pharmacy regulator into believing that his English had reached a safe standard when it had not the most important and serious of the allegations. The Committee ordered Mr Y to be removed from the Register of Pharmacists. The Direction was made on 23 May 2011 and an interim order imposed until the direction for removal comes into effect.

Case 2

The case of Mr M concerns allegations of a number of dispensing errors and of a lack of competency in the English language. The case concluded with the Disciplinary Committee directing Mr M's removal from the Register of Pharmacists. The language allegations were that he accepted employment as a locum pharmacist at three pharmacies when he did not have the requisite skills and fitness for the task to be performed, contrary to part 2A1(a) of the code, in that he lacked sufficient competency in the English language. The evidence of lack of competency was provided by his colleagues and one patient; one colleague said that, in her view, Mr. M had difficulty in making himself understood, a patient said that Mr. M's command of English was not very good; another colleague said that Mr. M's English would be best described as broken, and there were gaps when he spoke while he appeared to think what he was going to say; another colleague said "I do not think that his English was very good. I sometimes found him difficult to understand".

There were however evidential difficulties in establishing that the registrant's command of English was so deficient that he was guilty of misconduct by virtue of having accepted locum work as a community pharmacist. The committee did not find any of the language allegations proved, on the ground that Mr M had been interviewed before being offered work and the interviewers had considered Mr M's English language skills to be sufficient.