

Response to DH Consultation on the European Commission's proposals for a Directive on the application of patients' rights in cross-border healthcare

The Royal Pharmaceutical Society of Great Britain (RPSGB) is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under anticipated legislation.

The primary objectives of the RPSGB are to lead, regulate, develop and represent the profession of pharmacy.

The RPSGB leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

Following the publication in 2007 of the Government White Paper Trust, Assurance and Safety - The Regulation of Health Professionals in the 21st Century, the Society is working towards the de-merger of its regulatory and professional roles. This will see the establishment of a new General Pharmaceutical Council and a new professional body for pharmacy in 2010.

We wish to respond to the following questions:

1. Common principles in all EU health systems

Question 1

What role (if any) should the Commission have in setting standards for cross-border healthcare?

1.1 The stated aim of the proposed Directive is to:

'establish a general framework for the provision of safe, high-quality and efficient cross-border healthcare in the European Union and to ensure free movement of health services and a high level of health protection'

A framework which provides clarity is needed and deserves to be supported in principle.

1.2 The role of the Commission should be to set overarching principles which should apply to all forms of cross-border healthcare but the responsibility for setting standards for safe and high quality provision of health care should rest with the individual Member States so they can best take account of the domestic health system, cultural considerations and patient safety.

1.3 In the proposed Directive treatment is to be provided in accordance with the legislation and standards of the Member State of treatment. This principle should apply to all forms of cross-border healthcare. Where this principle conflicts with provisions in Directive 2005/36/EC and Directive 2000/31/EC this principle in relation to cross-border healthcare services (as set out in pre- amble 10 of the proposed Directive) should arguably take precedence. This will ensure that the principle is applied consistently to all forms of cross-border healthcare and will provide clarity and certainty for patients.

At present under Directive 2005/36/EC when the patient does not cross borders to receive care but instead the healthcare practitioner moves to provide care on a temporary and

occasional basis, the patient may assume that the standards applied to the practitioner's right to practise are governed by the Member State where the treatment is received. This is not the case. Currently a temporary healthcare provider's right to practise is based on his subsisting right to practise in his home Member State of establishment. That State may have different standards of fitness to practise and continuing assurance of competence than the host Member State regulator.

The proposed Directive should provide that the standards to be applied in all circumstances are those of the Member State of treatment. Directive 2005/36/EC should not be excluded from this principle. This would enable a healthcare regulator to assess the temporary service provider against the same fitness to practise and continuing competence criteria used to assess practitioners established or wishing to become established in the host Member State.

1.4 Furthermore although preamble 10 sets out that cross-border healthcare includes:

'cross-border provision of healthcare (ie delivery of service from the territory of one member State into the territory of another).....'

and

'Permanent presence of a healthcare provider (i.e. establishment of a healthcare provider in another Member State)

It would not appear that these 2 examples of cross-border healthcare are covered by the definition of cross-border healthcare in Article 4 of the proposed Directive.

2. Use of healthcare in another Member State

Question 3

How can the UK Government ensure that these proposals do not adversely affect the NHS's ability to plan and manage services (including the ability to retain appropriate 'Gatekeeping' arrangements)? Should prior authorisation schemes be the norm rather than the exception?

2.1 The proposed Directive is in addition to systems which already exist under a cooperation agreement between all of the EU's social security systems provided by Regulation 1408/71.

This Regulation includes

- the European Health Insurance Card which covers citizens facing a health problem while studying or travelling in a Member State other than their home country and enables them to obtain medical treatment and be reimbursed for this, and also
- persons who cannot get the healthcare they are entitled to in their own country within a reasonable time can be authorised to go abroad and the costs of their treatment abroad will be covered.

The existing Regulation reimburses the full cost of treatment, whereas if patients elect to go for treatment to another Member State under this proposed Directive the level of reimbursement is capped to the cost of the treatment which the patient would have been

entitled to had the treatment been provided in their Member State of affiliation. Under the proposed Directive patients bear the financial risk of any additional costs arising.

2.2 What falls within the definition of 'within a reasonable time' will continue to be the subject of legal argument and lead to uncertainty. This Directive does not address this and arguably it will be the affluent patient who can afford the risk of paying additional costs who will take advantage of the Directive provisions.

2.3 The Directive proposal would benefit from a clearer definition of what will be deemed to be "hospital care", in the context of the prior authorisation provisions. For example a procedure that in one Member State may be considered to require an overnight stay in a hospital or similar establishment, might routinely be accomplished in another Member State as a day case.

2.4 In addition to the lack of clarity surrounding the definition of 'hospital care' and 'within a reasonable time', it is also unclear whether prior authorisation for hospital care can be imposed from the outset or only if there is evidence that the provisions of the Directive are having a destabilising effect on healthcare provision in the home Member State.

2.5 Prior authorisation will assist in controlling 'outflow' of patients but there appear to be no provisions to control 'inflow' of patients. Excessive 'inflow' could equally affect the ability of the NHS to plan and manage services. Unrestricted 'inflow' of patients could have a detrimental effect on services provided to Member State nationals.

2.6 The proposed Directive contains the following statements which are potentially inconsistent:

At page 9 it is stated that

'the proposal does not change the right of Member States to define the healthcare benefits that they choose to provide to their citizens. If a Member State does not include a particular treatment as part of the entitlement of their citizens at home, this mechanism does not create any new entitlement for patients to have such treatment abroad and be reimbursed'

However at page 28 preamble 27 states

'This Directive provides also for the right for a patient to receive any medicinal product authorised for marketing in the Member State where healthcare is provided, even if the medicinal product is not authorised for marketing in the Member State of affiliation, as it is an indispensable part of obtaining effective treatment in another Member State'

Would treatment with the medicinal product which is not licensed in the Member State of affiliation be reimbursed under the proposed Directive?

Also, this may have a detrimental effect on continuity of care in circumstances where treatment may need to continue with an 'unlicensed medicinal product' on the patient's return to his Member State of affiliation.

2.7 Another complicating factor is that the issue of reimbursement is a devolved issue in the UK. Some medicinal products may be reimbursable under the NHS in Scotland but not in England for example.

2.8 A relevant factor to possibly also consider here is Government policy relating to top-up payments. If patients are permitted to top up their healthcare by buying medicines that have been ruled too expensive to be made available on the NHS this would permit patients to pay for these medicines irrespective of whether they had been prescribed in the UK or another Member State and continue to receive NHS/reimbursable healthcare.

Question 7

What information, and presented in what format(s), do you think patients need to make an informed decision on receiving treatment in another EU Member State?

3.1 The Directive recognises that patients need to have clear detailed information about:

- *The system of healthcare in other Member States to enable them to make an informed decision about where they want to receive treatment.*

The Royal Pharmaceutical Society of Great Britain has a particular interest in the position of health care professionals in relation to patient safety.

When patients cross borders to receive treatment or when health professionals cross borders to provide services to ‘ensure a high level of health protection’ there has to be a high degree of cooperation and exchange of information concerning not only the system of health care in the host Member State and the patient’s medical history for example, but also information concerning the health professional’s fitness to practise and assurance of current professional competence and language competence.

If there is no legal requirement for healthcare regulators to have real-time web-based publicly searchable lists of registered professionals with an assurance that those whose names appear on the register are fit to practise (preferably in accordance with character and health checks such as those required by UK regulators) patients will not be able to make an informed decision about where and from whom they wish to receive treatment.

The proposal should introduce a requirement for healthcare regulators to establish real-time web-based publicly searchable lists of registered professionals with an assurance that those whose names appear on the register are fit to practise. Any conditions or restrictions on practice should also be publicly available.

3.2 The proposal should require healthcare regulators in other Member States to disclose fitness to practise information

- on practitioners who practise in their own Member State and
- on practitioners who wish to move to another Member State to practise.

Healthcare Professionals Crossing Borders (HPCB) which is an informal partnership of professional regulators from within Europe has worked collaboratively to encourage information disclosure and exchange but has found that although Directive 2005/36/EC requires collaboration on information exchange some regulators are prevented from doing so because of rigid national interpretations of data protection legislation.

To ensure transparency about applicable standards for patients and professionals the proposed Directive should include a legal duty on regulators to disclose and exchange relevant regulatory information.

This would ensure that patient safety is central to the free movement of patients and health professionals in Europe.

3.3 Additionally patients will need assurance that the healthcare practitioners will be able to communicate with them in their own language.

3.4 Information on the system of healthcare should also include the scope of practise of the health care professionals in the Member State of treatment as this may be different to what the patient is used to in their Member State of affiliation.

3.5 The proposed Directive should also include provisions relating to revalidation to provide assurance to patients and regulators of current practitioner performance competence when practitioners seek to practise in other Member States.

- *Who is going to be responsible for the continuity of their care and what will the continued treatment plan involve.*

3.6 Communication of healthcare information from e.g. secondary to primary care (or vice versa) even within the UK can be delayed or be incomplete. This information exchange may be subject to potentially greater delays, errors and miscommunications when information is transferred between professionals /organisations in different Member States. Language may be a barrier, names of medicines, doses and treatment and prescribing protocols may be different, all of which could hinder safe and effective continuity of care.

3.7 Patients need to know not only who will be responsible for their continued treatment but also how and when information about the continued treatment plan will be communicated and that all relevant treatment information will be communicated promptly and accurately in the appropriate language to facilitate continuity of care.

3.8 There is also a need for prescriptions written by UK-registered nurse / pharmacist prescribers to be recognised in other Member States, as non-recognition could hinder continuity of treatment for the patient.

- *Mechanisms to ensure appropriate remedies and compensation for harm arising from healthcare.*

3.9 The proposed Directive states that for the purposes of clarity the *'rules applicable to the actual provision of healthcare is governed by the rules of the Member State of treatment'* (p 18). If something goes wrong, patients would be guaranteed redress and compensation, according to the rules of the country where treatment was provided. In cross border prescriptions if something goes wrong and the patient suffers harm – what is the Member State of treatment? Is it the Member State where the clinical decision that a particular medicinal product is appropriate for the patient's condition is made and the prescription is written or is it the Member State where the prescription is ultimately dispensed and treatment actually begins.

3.10 Doctors and pharmacists share responsibility. There are at least 2 High Court decisions where liability for harm caused has been assigned, proportionately to the extent of their individual contributory negligence, to both the pharmacist and the prescriber.

Is the patient to get redress and compensation, according to the rules of the country where the prescription was written or according to the Member State where the prescription was dispensed?

3.11 In relation to appropriate remedies and compensation, it is difficult enough to prove causation and obtain redress for harm arising within a single jurisdiction. It would be even more complex when this is across jurisdictions.

4. Co-operation on healthcare

Question 9

Is an EU prescription template feasible and what would it look like? What advantages and disadvantages could there be to this?

4.1 An EU prescription template is feasible but it will need to comply with the legislative requirements of all the Member States to ensure that it is legally valid across all jurisdictions.

4.2 In the UK a prescription issued by a doctor or dentist in another EEA Member State or Switzerland must satisfy all the conditions specified in Article 15 of the Prescription Only Medicines (Human Use) Order 1997 (POM Order).

Following the consultation on regulations to amend medicines legislation to permit pharmacists to dispense prescriptions issued by a doctor or dentist registered in an EEA country or Switzerland the European Commission raised an objection to the requirement for the EEA prescription needing to include the patient's address.

The Society's view which was passed to the Medicines and Healthcare Products Regulatory Agency was that the address of the patient is an important part of a prescription as it helps to identify the correct patient. As the POM Order only makes it a legal requirement for the prescription to include the date of birth if the patient is under 12 years old, the address is the only piece of information legally required on a prescription that enables a pharmacist to quickly distinguish between two patients with the same name.

When considering patient safety, the RPSGB cannot find justification in enabling doctors or dentists from EEA Member States or Switzerland to write prescriptions that contain less than the current requirements in the UK. This would be contrary to the wider public interest.

4.3 The advantages of European prescription template would be that all the legislative requirements could be incorporated. It could also include built-in translations for the various sections along lines similar to the format for birth certificate extracts under the convention signed at Vienna in 1976. This would assist the prescriber to enter

- their name and address, (and possibly phone number and e-mail address to facilitate contact between pharmacist and prescriber)
- the patient's name address and age if under 12,
- name form and strength of the medicinal product,
- dosage instructions,
- date of issue and signature

in the appropriate sections of the prescription.

Having a template would ensure that all the fields of data legally required on a prescription in the UK would be completed by an EEA or Swiss prescriber who is not familiar with our requirements.

- 4.4 Additionally details of the various regulator websites could be added. This would assist dispensing pharmacists to identify the organisations they should contact to verify that the prescriber is authorised to prescribe in their Member State.
- 4.5 A standard template may increase the risk of fraud and forgeries. Security features to prevent this should be incorporated.
- 4.6 A standard prescription template would not replace the checks that a pharmacist should complete to satisfy themselves that the prescription is authentic and that the prescriber is authorised to prescribe and that there are no restrictions placed upon the prescriber.
- 4.7 It is the RPSGB's understanding that very few EEA competent authorities have real-time web-based publicly searchable lists of registered practitioners. The proposed Directive should make it a requirement for Member States to have real-time web-based publicly searchable lists of registered professionals with an assurance that those whose names appear on the register are fit to practise.
- 4.8 Incorporating translations for the various sections of the prescription template will not overcome the language barriers which may be encountered when assessing the content of the prescription as a result of differences in drug names, variations in abbreviations used, dosages and directions.

For example if a pharmacist dispensed 'Acepril' marketed in the UK against a prescription for 'Acepril' issued in Switzerland the pharmacist would be supplying the medicine 'captopril' when the prescriber's intention was for the patient to receive 'enalapril'.

However had the prescription for 'Acepril' been issued in Denmark then the intended medicine for the patient would again not be 'catotpril' but 'lisinopril'.

The EU prescription template should require practitioners 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, it is important for the patient to continue on the same brand of medicine.

- 4.9 A pharmacist who needs to contact the prescriber to clarify any matter is likely to encounter additional language barriers, in trying to contact the prescriber in the first instance and also in communicating any queries they may have. The ability for the pharmacist and prescriber to communicate effectively and understand each other is of critical importance to enable pharmacists to be satisfied of the clinical appropriateness of medicines supplied to individual patients.

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