The Patient Mobility Directive and the Mutual Recognition of Prescriptions in the EU: A Cause for Concern for Patients and Pharmacists Alike?

Maria K. Sheppard[1]

Abstract

The law on the mutual recognition of prescriptions in the EU has been codified in two recent EU Directives, the Patient Mobility Directive, and the Implementing Directive. The objective is to improve access to medicines abroad benefitting, amongst others, patients with chronic diseases wishing to travel to another country and patients with rare diseases where the best expertise can often be found across a border. However, there are challenges for patient safety due to the increased risk of dispensing errors. These challenges concern, in particular, the identification of the prescriber and the prescribed medicines. There are also difficulties in the comprehensibility of prescriptions due to the different languages, drug names and abbreviations used in the EU. Although the Directives suggest the use of international non-proprietary names to reduce drug mistakes, this is not obligatory. With dispensing errors by pharmacists in England currently a criminal offence it is likely that pharmacists will hesitate dispensing cross-border prescriptions thus reducing the impact of the Directives.

Keywords

Cross-border healthcare, Patient Mobility Directive, patient safety, medical prescriptions, Implementing Directive, dispensing errors.

[1] Post-doctoral researcher, Law Department, Queen Mary University of London, Mile End Road, London E1 4NS

1. Introduction

The Directive 2011/24/EU on the Application on Patients' Rights in Cross-border Healthcare, also known as the Patient Mobility Directive was transposed into UK national law on 25th October 2013. It consolidates the case law of the Court of Justice of the European Union based on the market principles of the Treaty on the Functioning of the European Union (TFEU).[2] The Patient Mobility Directive provides a legal framework for cross-border healthcare amongst EU Member States with the aim of creating patients' rights in cross-border healthcare such as provisions regarding patients' entitlements, the reimbursement of the costs of cross-border treatment and the conditions for prior authorisation of cross-border healthcare.[3] At the same time it is concerned with the safety and quality aspects of cross-border healthcare[4] with Member States retaining responsibility for providing safe, high quality and efficient healthcare to EU citizens on their territory.[5] The EU rules on freedom to provide services under the TFEU also include the recognition of prescriptions which are issued by a healthcare professional legally entitled to do so in another EU Member State. The recognition of cross-border prescriptions aims to improve patients' access to medicines abroad. Such access is particularly important for patients with chronic diseases wishing to travel to another country, for patients living in border regions or smaller Member States for whom filling out a cross-border prescription is a necessity and for patients with a rare disease, where the best expertise can be found across a border.[6] As there were concerns about patients' ability to access medicines in other EU Member States under the freedom of movement rules[7] the Patient Mobility Directive incorporates a provision to facilitate the mutual

[2] Peeters, M. (2012) Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border Healthcare. *European Journal of Health Law*. 19 (1). p.29-60.
[3] Patient Mobility Directive, articles 7 and 8
[4] Ibid, article 1 para. 1 and 4. 1(b).
[5] Ibid, preamble 4.
[6] Van den Steen, D. (2013) Cross-Border Health Care: Common Rules on Medical Prescription when Travelling to another EU Country. *Eurohealth.* (19) 4. p.28-30.
[7] It is estimated that the total number of cross-border prescriptions in the EU is around 2.3 million per year which translated to 0.02 to 0.04 percent of all prescriptions in the EU, EUROPEAN COMMISSION PRESS RELEASE. (2012) *Europe for patients: Common rules on medical prescriptions when travelling to another EU country*. [Online] Available from http://europa.eu/rapid/press-release_IP-12-1422_en.htm. [Accessed: 10th October 2015].

recognition of prescriptions dispensed in another Member State. Thus Article 11 provides that where a medicinal product is authorised for use on their territory Member States shall ensure that prescriptions for the product issued in another Member State can be dispensed on their territory, or in other words the Article provides for mutual recognition of medicinal prescriptions in the EU. This paper explores whether the consolidation of the freedom of movement rules regarding prescriptions in the Patient Mobility Directive removes the obstacles for the mutual recognition of prescriptions in England, Scotland and Wales. It discusses the possible challenges to patient safety due to the increased risk of dispensing errors regarding the identification of the medicinal products, of the prescriber and of the patient. Furthermore the paper considers whether the willingness of community pharmacists to run the risk of incorrect dispensing of cross-border prescriptions might not be affected by current legislation in England criminalising the dispensing errors of pharmacists.[8] It is left open whether the intended decriminalisation of dispensing errors to be linked with the requirement for pharmacists to report these errors on a non-anonymised basis in the future will improve the low domestic dispensing rate of cross-border prescriptions.[9]

Mutual recognition of medical prescriptions in the EU

Article 11 of the Patient Mobility Directive not only authorises the mutual recognition of medicinal prescriptions in EU Member States and the dispensing of the prescribed medicinal products, it prohibits restrictions on the recognition of individual prescriptions. There are exceptions to this prohibition, namely where the restriction is limited to what is necessary and proportionate to safeguard human health and the restriction is non-discriminatory[10] or where the restriction is based on legitimate and justified doubts about the authenticity, content or comprehensibility of an individual prescription.[11] In order to facilitate the implementation of the mutual recognition of prescriptions, Article 11 further provided for

[8] Medicines Act 1968, s. 67 (2).
[9] Pharmaceutical Services Negotiating Committee. (2015) *Patient Safety Incident Reporting*. [Online] Available from: http://psnc.org.uk/our-news/settlement-201415-update-patient-safety-incident-reporting/. [Accessed: 28th October 2015].
[10] Ibid, Article 11. 1(a).
[11] Ibid, Article 11. 1(b).

the EU Commission to adopt an Implementing Directive laying down measures aiding the recognition of cross-border prescriptions.[12] The Implementing Directive[13] which was transposed into national law at the same time as the Patient Mobility Directive, introduces a minimum list of elements to be included in the prescription. This non-exhaustive list covers relevant information which is to enable a pharmacist to verify the authenticity of a prescription from another Member State. The information is intended to help with the identification of the medicinal product prescribed, of the prescribing healthcare professional and of the patient.

a) The identification of the medicinal product

In order to facilitate the correct identification of medicinal products which are marketed under different brand names across the EU, and of products that are not marketed in all EU Member States, the Implementing Directive states that medicinal products should be indicated using the common name, namely the International Non-Proprietary name (INN) recommended by the World Health Organisation (WHO) or, if such a name does not exist the usual common name.[14] Two exceptions are included in the Preamble. Firstly, the branded name of a product can be used if it is a biological medicinal product.[15] Secondly, it can be used if the prescribing healthcare professional deems a brand name product medically necessary as long as he or she states the reasons justifying the use of the brand name product. Brand names of medicinal products tend to vary across the EU and country-specific brand names may be the main obstacle for a product not to be dispensed across borders.[16] Prescription by brand names, driven to a large extent by the pharmaceutical industry's marketing to prescribers, is common in many EU Member States and substitution of a brand name product with an equivalent generic product is forbidden in some Member States.[17] Where the domestic legislation permits the substitution of branded

[12] Ibid, Article 11. 2(a).
[13] Commission Implementing Directive 2012/52/EU laying down measures to facilitate the recognition of medical prescriptions issued in another Member State, hereinafter 'the Implementing Directive'.
[14] Ibid, preamble 4.
[15] A biological medicinal product is defined in point 3.2.1.1 (b) of Annex 1 to the Directive 2001/83/EC relating to medicinal products for human use.
[16] Baeten, R. & San Miguel, L. (2013) Cross-Border Recognition of Medicines Prescriptions: Results from a Mystery Shopping Experiment. *Eurohealth.* (19) 4. p.12-13.
[17] Ibid; but see the experience in Scotland achieving reduced drug costs because of the high voluntary prescribing rates of INNs in Goodman, B. et al (2013) Reforms and Initiatives in Scotland in recent years to

products there are safety concerns regarding their substitution. In some countries there is also a tendency to use branded fixed dose combinations containing two or more active substances in a single product[18] which although convenient for patients also often has the advantage for the pharmaceutical industry of achieving additional data exclusivity of the soon to expire data exclusivity of an approved mono-substance.[19] It will often be impossible to split these drugs into their separate components while keeping to the dosages of the components in the fixed combination product. There are also differences in generic drug names across the EU and the further problem that different drugs are available in different EU Member States.[20]

The use of a brand name or a different generic name on a cross-border prescription could be a concern since current European medicines regulations regarding the naming for medicinal products do not consider all aspects pertaining to patient safety adequately even on their own territory. Medication errors where the incorrect drug is dispensed occur not infrequently in all European Member States because of sound-alike or look-alike drug names.[21] These medication errors, by definition preventable, can lead to serious adverse drug events and pharmacists are advised to contact prescribers in case of any doubt before dispensing the medicine.[22] For community pharmacists dealing with prescriptions of medicinal products from other Member States the risk of such errors is likely to be higher because of the greater

encourage the prescribing of generic drugs, their influence and implications for other countries. *Expert Rev. Pharmacoecon. Outcomes Res*. 13 (4). P.469-482.

[18] EMA. (2015) *Guideline on clinical development of fixed combination of medicinal products*. [Online] Available from: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2015/05/WC500186840.pdf. [Accessed: 24th October 2015].

[19] EMA (2013) *Data exclusivity, market protection and paediatric rewards*. [Online] Available from: http://www.ema.europa.eu/docs/en_GB/document_library/Presentation/2013/05/WC500143122.pdf. [Accessed: 24th October 2015].

[20] House of Lords Select European Union Committee. (2009). *Healthcare across Borders: a safe framework*. [Online] Available from: http://www.publications.parliament.uk/pa/ld200809/ldselect/ldeucom/30/3002.htm. [Accessed: 10th October 2015].

[21] Council of Europe, Expert Group on Safe Medication Practices (P-SP-PH/SAFE). (2006) *Creation of a better medication safety culture in Europe: Building up safe medication practice.* [Online] Available from: http://www.coe.int/t/e/social_cohesion/soc-sp/medication%20safety%20culture%20report%20e.pdf. [Accessed: 20th October 2015].

[22] NICE (2013). *Medicines Evidence Commentary, MHRA drug safety update: drug-name confusion reminder.* [Online] Available from: file:///C:/Users/User/Downloads/MEC+-+MAW+12+August+2013%20(2).pdf. [Accessed: 20th October 2015].

difficulty to recognise the branded name. This would be even more so where the unfamiliar branded name of the cross-border prescription resembles that of a more familiar local preparation. There is therefore clearly a need for the dispensing pharmacists to be able to identify and contact the prescriber if they realise the problem.

The decision by the European Commission to use WHO INNs which are unique names globally recognised should help to avoid confusion.[23] Their use standardises the naming of medicines at an international level and aids communication between medical prescribers and dispensing pharmacists. Although the WHO INN Programme helps to verify the safety of the INNs and avoid confusion errors between INNs, medication errors related to their use have been reported.[24] Confusion with a new proprietary name is, for example, possible where there is a look- or sound-alike brand or proprietary name which is already registered. The use of INNs is, however, preferable to the use of brand names in order to reduce medication errors with the greatest risk being the alternate use of generic and brand names for the same product. One such example, discussed by the House of Lords European Union Committee is a medicine with the generic name captopril, which is marketed in the UK as Acepril. The correct generic name for Acepril in Switzerland is enalapril and in Denmark, it is lisinopril.[25]

To identify the medicinal product, according to the Annex of the Implementing Directive, other minimum elements need to be included on the cross-border prescription, such as the formulation of the product, strength, quantity and dosage regime. A challenge for the dispensing pharmacists could be handwritten prescriptions, those presented in an unfamiliar language or alphabet, or missing information.[26] Medication errors may of course also arise where the pharmacist dispenses the correct drug but at an incorrect dose or an incorrect formulation which is more likely with a cross-border prescription because of the variation in the abbreviations used. Where the pharmacist decides against dispensing the medicinal product because of insufficient information on the prescription the patient

[23] Supra, note 16.
[24] Supra, note 22.
[25] Supra, note 20.
[26] Supra, note 6.

risks a medication gap with possible untoward consequences. It is therefore paramount that the prescriber cannot only be identified but also contacted.

b) Identification of the prescriber

The Implementing Directive contains a non-exhaustive list of elements dealing with the authentication of the prescribing healthcare professional. Amongst these are the surname(s), first name(s) written out in full, professional qualification, details for direct contact including (email, telephone or fax), the work address (including the name of the relevant Member State) and the written or digital signature of the prescribing healthcare professional.[27] Where some of this information is missing and the pharmacist is unable to verify the authenticity of the prescriber they may of course refer the patient to a local doctor to obtain a new prescription to limit the risk of dispensing against a false prescription. However, products containing narcotic substances which could lead to addiction or illegal use, i.e. controlled drugs, were excluded from the ambit of the Patient Mobility Directive. Under Article 11(6) they come within the scope of medicinal products subject to special medical prescription.[28]

c) Identification of the patient

The Annex of the Implementing Directive also includes a non-exhaustive list of elements to help identify the patient. These are the surname(s), the first name(s), written in full and the patient's date of birth. Like the authentication of the prescribing health professional and of the prescription the patient identification from the prescription will need to be verified by pharmacists. Unlike where a patient is a resident in the UK and has a prescription from a doctor resident in the UK where it is sufficient to identify patients by asking them to confirm their address and/or their date of birth[29] pharmacists will

[27] Commission Implementing Directive 2012/52/EU, Annex.
[28] Patient Mobility Directive, Article 11(6) required an amendment of the Human Medicines Regulations 2012 where "controlled drug" was substituted with "medicinal products subject to special medical prescription". The Human Medicines Regulations 2014, SI 2014 No. 490, reg. 217A also includes the list of elements in cross-border prescriptions to authenticate the prescriber when the UK resident patient crosses to border to another EU Member State.
[29] Royal Pharmaceutical Society of Great Britain (2009). *Good dispensing Guidelines – England*. [Online] Available from: http://www.rpharms.com/practice--science-and-research/good-dispensing.asp. [Accessed: 10th October 2015].

need to have a procedure for identifying patients with a cross-border prescription such as a passport, a national ID card from one of the EU Member States or a driving licence.

Problems in dispensing prescriptions for community pharmacists in the UK

Despite the EU rules on freedom of the provision of services Article 11 of the Patient Mobility Directive recognises the right of pharmacists to refuse to dispense a cross-border prescription for ethical reasons if the national rules recognise this right for a medical prescription issued in the home Member State. Thus if the pharmacists would have the right to refuse to dispense a domestic prescription for ethical reasons they can also do so in the case of a cross-border prescription.

In England, Scotland and Wales pharmacists are bound by the Standards of Conduct, Ethics and Performance of the General Pharmaceutical Council (GPC), the independent regulator for pharmacists in Great Britain.[30] Failure to follow these Standards can put the registration of the pharmacist at risk. The first two principles of these Standards for pharmacists are to "make patients [their] first concern" and to "use [their] professional judgment in the interests of patients and the public".[31] In order to meet these Standards pharmacists must "use their professional judgement when deciding on a course of action".[32] Most importantly, when "faced with conflicting professional or legal responsibilities" pharmacists "must consider all possible courses of action and the risks and benefits associated with each one to decide what is in the best interests of patients and the public".[33] Likewise, according to the Code of Ethics for Pharmacists and Pharmacy technicians of the Royal Pharmaceutical Society of Great Britain (RPSGB), the dedicated professional body for pharmacists in Great Britain,[34] is mandatory. It is slightly more detailed in its guidance and emphasises that pharmacists seek all relevant information required to assess an individual's needs and provide appropriate treatment and care. Where necessary,

[30] General Pharmaceutical Council. (2012) *Standards of Conduct, Ethics and Performance*. [Online] Available from: https://www.pharmacyregulation.org/standards/conduct-ethics-and-performance. [Accessed: 10th October 2015].
[31] Ibid, principles 1 and 2.
[32] Ibid, page 6.
[33] Ibid, page 7.
[34] Royal Pharmaceutical Society of Great Britain. (2007) *Code of Ethics for Pharmacists and Pharmacy Technicians.* [Online] Available from: http://www.rpharms.com/code-of-ethics-pdfs/coeppt.pdf. [Accessed: 10th October 2015].

they must refer patients to other health or social care professionals or other relevant organisations.[35] They must also seek to ensure safe and timely access to medicines and take steps to be satisfied of the clinical appropriateness of medicines supplied to individual patients.[36] Both bodies have developed additional guidance regarding the dispensing of medicine which state that accurate dispensing is fundamental for the practice of pharmacy. Thus the RPSGB has developed 'Good Dispensing Guidelines' and a guidance on 'Professional Standards and Guidance for the Sale and Supply of Medicines' whereas the GPC has issued a guidance note 'Responding to Complaints and Concerns', a guidance which includes advice on how to minimise the risk of a dispensing error occurring.

Dispensing errors do, however, occur although the number of cases can only be estimated. Dispensing errors are thought to be an everyday occurrence.[37] They include misreading the prescription, incorrect picking of the medicines or selecting the wrong strength or dosage or the wrong preparation. Such errors are much more likely with a cross-border prescription in an unfamiliar language and unfamiliar branded, possibly sound-alike products. Between April 2009 and March 2010 the GPC's Investigating Committee discovered around 200 cases which were declared dispensing errors. 60 of these cases were considered by the Disciplinary Committee of the GPC.[38] Since 2005 pharmacists in England have been required to report patient safety incidents to the National Reporting and Learning Service (NRLS) with the planned introduction of reporting on a non-anonymised basis.[39] Under the Medicines Act 1968 dispensing errors by pharmacists constitute a criminal offence,[40] i.e. the contravention of the obligation to dispense only in accordance with the terms of a medical practitioner's prescription.[41] The offence is punishable by a fine and/or imprisonment not exceeding two years.[42] It is therefore not surprising

[35] Ibid, article 1.4.
[36] Ibid, article 1.5.
[37] Supra, note 9.
[38] General Pharmaceutical Council. (2010) *Responding to Complaints and Concerns. Guidance note.* [Online] Available from: http://www.pharmacyregulation.org/sites/default/files/Responding%20to%20complaints%20and%20concerns%20g.pdf. [Accessed 10th October 2015].
[39] The non-anonymisation requirement has now been delayed until dispensing errors have been decriminalised, supra note 9.
[40] Medicines Act 1968, s. 67(2).
[41] ibid, s. 58 (2).
[42] Ibid, s. 67(4).

that the number of reported patient safety incidents in the form of dispensing errors has been very low. Although work is currently carried out by the Pharmacy Regulation Programme Board with the intention to change medicines legislation and to decriminalise dispensing errors by pharmacists and delay the introduction of non-anonymised reporting of patient safety incidents this is unlikely to happen until 2016.[43]

Despite the objective of the two Directives to give patients access to their medicines across borders inaccurate dispensing has the potential to put patients at risk. Clearly the aim of national legislation and the ethical guidance must be above all to ensure patient safety and the safe dispensing of medicines to the public. The national rules are likely to make pharmacists overall more inclined to refuse to dispense drugs on a cross-border prescription where accurate dispensing is in any doubt. Cross-border patients may then need to visit a healthcare professional in the UK to obtain a local prescription, time consuming for patient, healthcare professional and costly for EU healthcare systems.

Conclusion

As has been explained there are a multitude of risks with the dispensing of cross-border prescriptions for patients as well as pharmacists. Some aspects regarding prescriber authentication, patient identification and, most importantly, the identification of the medicinal products have been addressed by the Implementing Directive although challenges remain. For example, regarding the authentication of prescribers only a web-based searchable register of prescribers entitled to prescribe medicines would reduce the risk of false prescriptions being dispensed. Regarding the identification of medicinal products the use of WHO INNs should help to avoid confusion in most cases but, as has been discussed prescribers may continue to use brand name drugs or drugs with generic names not recognised in the UK. In addition challenges to patient safety remain due to the different languages, alphabets and abbreviations in different EU Member States and the use of hand-written prescriptions. Whether electronic prescribing or e-prescriptions exchanged by providers through e-mail or e-health systems would solve these issues is debatable but it would be a step in the right direction. Dispensing errors in

[43] Supra, note

pharmacies are an everyday occurrence even with local prescriptions. With the current criminalisation of dispensing errors in England and the number of incidents reported to the NRLS therefore much lower than expected it is unlikely that the Patient Mobility Directive and its Implementing Directive will achieve their objective and remove all the obstacles for the mutual recognition of cross-border prescriptions. This may not be convenient for the cross-border patient wishing to access medicines abroad but will not be detrimental to the safety of the cross-border patient.