

## ***Title page***

### ***Obstacles to the recognition of medical prescriptions issued in one EU country and presented in another: An observational study***

***Lorena San Miguel<sup>1</sup>, Rita Baeten<sup>2</sup>, Roy Remmen<sup>3</sup>, Reinhard Busse<sup>4</sup>, Joan Gil<sup>5</sup>, Cecile Knai<sup>6</sup>, Mia Mäkinen<sup>7</sup>, Gloria Rubert<sup>8</sup>, Martin McKee<sup>9</sup>***

1. Researcher, European Social Observatory (OSE), Rue Paul Emile Janson 13, Brussels 1050, Belgium
2. Senior Policy Analyst, European Social Observatory (OSE), Rue Paul Emile Janson 13, Brussels 1050, Belgium
3. Professor of General Practice at the Department of Primary and Interdisciplinary Care of the University of Antwerp, Campus Drie Eiken, Antwerp 2610, Belgium
4. Professor, Department of Health Care Management, Technische Universität Berlin, Strasse des 17. Juni 135, 10623 Berlin, Germany
5. Associate lecturer, Department of Economic Theory and Centre d'Anàlisi Econòmica i de les Politiques Socials (CAEPS), University of Barcelona (UB), Ave. Diagonal 690, 08034 Barcelona, Spain
6. Lecturer in European Health Policy, London School of Hygiene and Tropical Medicine, 5-17 Tavistock Place, London, UK
7. Senior Research Fellow, National Institute for Health and Welfare (THL), P.O. Box 30, FI-00271 Helsinki, Finland
8. Associate lecturer, Department of Economic Theory and Centre d'Anàlisi Econòmica i de les Politiques Socials (CAEPS), University of Barcelona (UB), Ave. Diagonal 690, 08034 Barcelona, Spain

9. Professor of European Public Health, London School of Hygiene and Tropical Medicine, 5-17  
Tavistock Place, London, UK

Correspondence to: sanmiguel@ose.be; Rue Paul Emile Janson 13, Brussels 1050;

Tel +32 475808394; Fax: +32 2539 28 08

***Funding and conflicts of interest***

The research leading to these results has received funding from the European Commission Seventh Framework programme (FP7/2007-2013) under grant agreement n° 242058, grant acronym EUCBCC, ECAB project. Sole responsibility lies with the authors and the European Commission is not responsible for any use that may be made of the information contained therein. No financial relationship exists with any organisations that might have an interest in the submitted work in the previous 3 years; no other relationships or activities that could appear to have influenced the submitted work.

Abstract word count: 85

Overall word count: 2982 without abstract, key points, acknowledgements conflict of interest and references

## **ABSTRACT**

A study involving the presentation of 192 Belgian or Finnish prescriptions in pharmacies in another member state was undertaken to assess whether, as envisaged by European Union law, prescriptions issued in one member state are recognized by pharmacists in another and to identify factors that influence such decisions. Results show important differences depending on the country where prescriptions are presented. Willingness to dispense was higher when prescriptions were written by INN and in English, as opposed to prescriptions written by brand in a national language.

### ***Key words***

Mutual recognition, cross border prescribing, dispensing, INN prescribing, EU law

## ***Introduction***

The 2011 European Union (EU) Directive on the application of patients' rights in cross-border healthcare requires that someone presenting a prescription issued in one member state should be able to have it issued in another, subject to any relevant national legislation.<sup>1</sup> However, there is very little evidence on whether this works in practice. It is estimated that 17 % of pharmacists in the EU are confronted with a foreign prescriptions more than 5 times a month, with much variation among member states.<sup>2</sup> Only one study, published in 2001<sup>3</sup>, addressed this issue and it involved only 28 pharmacy visits and prescriptions for a single, widely used, antibiotic. We describe the experience of presenting prescriptions from abroad in five EU member states.

## ***Methods***

Prescriptions issued in Belgium and Finland were presented to pharmacists in Belgium, Finland, Germany, Spain and the United Kingdom (UK) between October 2011 and February 2012. These countries represent different types of health system and account for 41% of the EU27 population<sup>4</sup>. Clinical scenarios were developed for three chronic disorders<sup>5,6,7</sup> (i.e. asthma, secondary prevention after myocardial infarction, and type II diabetes) and one acute condition (inhibition of lactation) that could realistically require care while abroad. No potentially problematic/unsafe medicinal products, were included in our research (see web appendix for detailed methodology).

## ***Results***

All 48 prescriptions presented domestically as controls (in Belgium and Finland) were dispensed, compared with 56% (108) of the 192 foreign prescriptions in the five counties ( $p < 0.001$ ).

The type of prescription influenced the willingness to dispense; pharmacists were willing to dispense 71% of prescriptions written by molecule in English and only 42% of those written by brand in a local language ( $p < 0,001$ ).

Willingness to dispense also varied according to the country where prescriptions were presented ( $p < 0,001$ ) with pharmacists in the UK and Finland least likely to dispense (only 29% and 33% of foreign prescriptions dispensed respectively), and German, Belgian and Spanish pharmacists most likely (79%, 67% and 67% of foreign prescriptions dispensed respectively). Location of pharmacy and patient condition made no difference.

The main reasons given by pharmacists in Finland and the UK related to their understanding of national legislation, with most Finnish pharmacists correctly reporting that they are legally restricted from dispensing non-Nordic prescriptions. However, British pharmacists also believed that the law barred them from dispensing foreign prescriptions, even though they are not.

Only four UK pharmacists unwilling to dispense gave reasons other than national legislation (i.e. product not in stock or not being sure about the dosages or strengths written on the prescription).

In Finland only two pharmacists who refused gave reasons other than not being able to dispense non-Nordic prescriptions as their main reason: difficult to validate the prescription, INN name written on the form not understood.

In the remaining countries, where willingness to dispense was higher, the main reason for not dispensing was their inability to recognize the product name written on the prescription, typically a country-specific brand name. Five pharmacists in these countries gave other reasons not to dispense, (i.e. inability to understand hand writing or a belief that foreign prescriptions could not be dispensed).

The right molecule was dispensed in all cases but brands and pack sizes sometimes differed from the prescribed ones. Pharmacists performed checks in over half of the visits (53 %), the most common involved searching in specific national databases (67% of all checks), while the second most common check was to search in the internet (33% of all checks). Seventeen percent of the checks included phone calls or direct consultation with managers, peers or authorities and only 11% of checks included searches of formularies or guidance documents.

Pharmacists questioned the researcher in 65% of the visits. Questions about the origin of the prescription were asked in over half (52%) of visits. Medical questions were less common (24% of visits). Pharmacists were slightly more likely to raise questions during visits in which prescriptions used brand names and were written in a national language.

The practically unanimous recommendation given by pharmacists unwilling to dispense was to visit a local GP.

## ***Discussion***

Our research found that, although willingness to dispense varied greatly depending on the country where prescriptions were presented, over half of pharmacists were willing to dispense. Differences in national law and practices clearly split the countries into two groups, with Finland and the UK being less willing to dispense than Belgium, Germany and Spain. In our study, the main reasons not to dispense in Finland and the UK related to perceived or actual legislation. Once the Directive is implemented, such differences should disappear. Yet, clear guidelines on how pharmacists should respond to EU prescriptions will be necessary.

Reasons for not dispensing in the remaining countries were primarily linked to the impossibility of identifying the correct product when pharmacists were presented with prescriptions using country-specific brand names. This obstacle appears to be key to dispensing. One obvious solution is for prescriptions written in the EU to use INNs. In the short term, an internet-based European product database allowing pharmacists to compare product names and identify the correct molecules would be very helpful. The verification of the authenticity of the prescription or the prescriber did not appear to play any role in the decision whether to dispense the product. We should recognise that our scenarios were for common conditions with few risks so our results should not be generalised to more complex cases in which the safety of the patient could be put at risk. Clear guidelines on the format of EU prescriptions, their minimum content, validity period, what to do or who to contact when confronted with them or what sources to consult on product composition and prescriber

credentials would be helpful and likely to have an impact not just on the availability of medication for citizens travelling to other member states, but also the time required for pharmacists to check the necessary information to dispense. Including the contact details of the prescriber in the prescription would have several benefits, including authentication of the prescriber and identification of the product if marketed under a different brand name.

The study was subject to geographical limitations. All visits were centred around one or two large cities. However, we have no reason to believe that the findings would differ if another region/area in the countries had been chosen.

It is not possible to ascertain whether the responses obtained in Germany may have been affected by the high refusal rate to participate (see web appendix). However, the authors of this study considered an ethical obligation to give the opportunity to pharmacists of refusing to take part in the study.

The sample size, although much larger than in the one previous study, is also a limitation.

Dosage differences between countries, although limited in our exercise, could be of greater importance in more dosage-dependent conditions.

To conclude, although more than half of the “patients” would have received their medication, there is still a long way to go before the Directive can be effectively applied in practice by pharmacists in all EU countries. There is clearly room for improving the current situation by developing measures to facilitate the duty of the dispensers while safeguarding the safety of patients.

**Table 1: Pharmacist willingness to dispense foreign (EU) prescriptions**

	DISPENSED*	NOT DISPENSED	TOTAL PRESENTED	DISPENSED (%)	NOT DISPENSED (%)	P VALUE
<b>Type of Pharmacy</b>						<b>0,565</b>
Centre	36	28	64	56,25	43,75	
Outskirts	33	31	64	51,56	48,44	
Rural	31	33	64	48,44	51,56	
<b>Patient case</b>						<b>0,838</b>
Asthma	29	19	48	60,42	39,58	
Myocardial infarction	25	23	48	52,08	47,92	
Diabetes	26	22	48	54,17	45,83	
Breast feeding inhibition	28	20	48	58,33	41,67	
<b>Country of origin</b>						<b>0,771</b>
Finnish**	55	41	96	57,29	42,71	
Belgian**	53	43	96	55,21	44,79	
<b>Type of prescription</b>						<b>0,000</b>
Brand in local language	40	56	96	41,67	58,33	
INN in English	68	28	96	70,83	29,17	
<b>Country where presented</b>						<b>0,000</b>
Belgium	16	8	24	66,67	33,33	
England	14	34	48	29,17	70,83	
Finland	8	16	24	33,33	66,67	
Germany	38	10	48	79,17	20,83	
Spain	32	16	48	66,67	33,33	
<b>TOTAL</b>	<b>108</b>	<b>84</b>	<b>192</b>	<b>56,25</b>	<b>43,75</b>	

\* includes "willing to order/dispense"

\*\*excludes controls

### Key Points

- The authentication of the prescription and prescriber does not seem to be an important issue when foreign (EU) prescriptions refer to relatively safe medical products.
- Willingness to dispense was higher when prescriptions were written as INN and in English, as opposed to prescriptions written by brand in another national language. There is a need for guidance on when and how to dispense such prescriptions.

### Acknowledgements:

The research leading to these results has received funding from the European Commission Seventh Framework programme (FP7/2007-2013) under grant agreement n° 242058, grant acronym EUCBCC, ECAB project. We would like to thank Philipp Dräger, Thierry Gahungu, Charlotte Hick, Régine Kiasuwa, Eleonora Lago, Verena Struckmann and Vesa Syrja for completing the pharmacy visits; to the Pharmaceutical Group of the European Union (PGEU) for facilitating the contact with national

pharmacist associations in the countries analysed; to the Federal Union of German Associations of Pharmacists (ABDA) in Germany, Belgian Pharmacists Association (APB) in Belgium, the association of Finnish Pharmacies in Finland, The Pharmacist Association of Barcelona (COFB) in Catalunya and The National Pharmacist Association (NPA) in England for providing us with contact details of the pharmacist in the relevant geographical areas.

We would also like to thank Uta Augustin, Ilmo Keskimäki and Dimitra Panteli for their general support and valuable feedback and Meritxell Solé for her active involvement in the early stages of the project.

### ***References***

---

1 Article 11, European Union. Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ 4.4.2011, p. L 88/45

2 Data based on a dispenser survey, personal communication... date...

3 Mäkinen M, Forsström J, Rautava P. Delivery of non-national prescriptions within the EU: How flexible is the common market for pharmaceuticals? *Eurohealth* 2001; 7(1):23-25

4 Eurostat (2012). Available from:

<http://epp.eurostat.ec.europa.eu/tgm/table.do?tab=table&language=en&pcode=tps00001&tableSelection=1&footnotes=yes&labeling=labels&plugin=1>. Retrieved on November 21st 2012

5 Busse R, Blümel M, Scheller-Kreinsen D et al. Tackling chronic disease in Europe: strategies, interventions and challenges. European Observatory on Health Systems and Policies; Observatory Studies Series N. 20; 2010

---

6 International Diabetes Federation. Prevalence estimates of diabetes mellitus (DM) 2010. Accesible from: [www.idf.org/content/eur-data](http://www.idf.org/content/eur-data)

7 European Society of Cardiology

European Cardiovascular Disease Statistics 2012-11-22

Accessible from <http://www.ehnheart.org/cvd-statistics/cvd-statistics-2012.html>