

## GOOD PHARMACY PRACTICE IN THE CONTEXT OF CROSS-BORDER HEALTHCARE

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### Abstract

Directives 2011/24/EU and 2012/52/EU include rules for facilitating the access of European citizens to safe and high-quality cross-border healthcare services, including the recognition of cross-border prescriptions. This paper aims to evaluate the impact of European provisions on the activity of pharmacists, who must comply with the requirements of good pharmacy practice. Comparative analysis and interpretation were used to this end. When providing cross-border healthcare, pharmacists must verify the authenticity and legality of prescriptions (compulsory elements established at European level, including elements to facilitate contact between healthcare professionals from different states). They must also evaluate the prescriptions (including the correct identification of medicinal products for their safe substitution) and provide quality information and assistance to patients (including measures to facilitate the comprehensibility of the information associated with the medicinal product). The paper suggests measures to facilitate the implementation of European provisions in order to provide high-quality pharmacy services in the context of cross-border healthcare. Pharmacists will have to adapt to new rules and instruments in order to ensure appropriate cross-border pharmaceutical care.

### Rezumat

Directivile 2011/24/UE și 2012/52/UE cuprind reguli pentru facilitarea accesului cetățenilor europeni la asistență de sănătate transfrontalieră, în condiții de siguranță și de calitate, inclusiv pentru recunoașterea prescripțiilor medicale transfrontaliere. Lucrarea are ca scop evaluarea impactului prevederilor europene asupra activității farmaciștilor, în condițiile respectării bunei practici farmaceutice. Pentru cercetare, s-au utilizat metodele interpretării și comparative. La eliberarea medicamentelor pe bază de prescripție medicală în context transfrontalier, farmaciștii trebuie să verifice autenticitatea și regularitatea tehnică a prescripției (elemente componente obligatorii stabilite la nivel european, inclusiv pentru facilitarea contactelor între profesioniștii din state diferite), să evalueze prescripția (inclusiv să identifice corect medicamentele prescrise, în vederea corectitudinii substituirii), să informeze și să consilieze corect pacientul (inclusiv prin optimizarea inteligibilității informațiilor asociate medicamentului). Pentru un act profesional de calitate, sunt necesare măsuri de facilitare a implementării prevederilor europene, propuse în lucrare. Farmaciștii vor trebui să se adapteze la utilizarea de noi reguli și instrumente pentru asigurarea calității în asistența farmaceutică transfrontalieră.

**Keywords:** cross-border healthcare, medical prescription, pharmacist, good pharmacy practice

### Introduction

Cross-border healthcare is defined, at the level of the European Union (EU), as healthcare provided or prescribed in a Member State (Member State of treatment) other than the patient's Member State of affiliation [7]. Regulation (EC) No. 883/2004 established the European legal framework for the coordination of social security systems, including healthcare [24], while Directive 2011/24/EU opened access to cross-border healthcare without prior authorization, by stating that European patients can choose their healthcare provider, including those established on the territory of a Member State other than that of affiliation, and be reimbursed for healthcare services provided in a Member State other than that of affiliation [7]. Directive 2011/24/EU and its first consequences were thoroughly analysed

by authorities [9, 10], as well as by the literature [1, 2, 17, 22, 23, 26-28, 31, 32], especially with regard to the impact of the provisions on healthcare services and the increased mobility of patients on the European territory, generally because of unavailable services in the state of affiliation, or the patient's desire to access better healthcare services than those offered in the state of affiliation. The impact of these provisions on the activity of community pharmacists was studied at a smaller extent. A comparative study on the legislations and practices of five Member States underlined the need to correctly manage the risks associated with dispensing cross-border prescriptions in order to ensure coherent and quality pharmacy care [25]. This field is highly important, since Directive 2011/24/EU proclaimed the recognition of medical prescriptions issued in a Member State other than

that of affiliation, without restrictions, except for when these restrictions are limited to what is necessary and proportionate to safeguard human health, and non-discriminatory; or are based on legitimate and justified doubts about the authenticity, content or comprehensibility of an individual medical prescription. However, the recognition of prescriptions shall not affect a pharmacist's right to refuse, for ethical reasons, to dispense a product, except for medicinal products subject to special medical prescription such as narcotics or psychotropic drugs [7]. In order to facilitate the recognition of prescriptions, the Directive stipulates that the European Commission must adopt measures that allow the authenticity of prescriptions to be verified, a greater interoperability of electronic prescriptions, the correct identification of prescribed medication, and a better intelligibility of the information associated with the prescription [7]. In this respect, the European Commission adopted the Implementing Directive 2012/52/EU laying down measures to facilitate the recognition of prescriptions issued in another Member State. The Directive established a non-exhaustive list of elements to be included in cross-border prescriptions, which refer to: patient identification data (first name, surname, date of birth), the authentication of the prescription (issue date), the identification of the prescribing health professional (first name, surname, professional qualification, details for direct contact – email, telephone, fax, work address, including the name of the state, written or digital signature, depending on the medium chosen for issuing the prescription), and data for the identification of the prescribed product (common name, pharmaceutical formulation, strength, quantity, dosage regimen, the brand name if the prescribed product is a biological medicinal product or the prescribing health professional deems it medically necessary, in which case the prescription will shortly state the reasons justifying the use of the brand name) [5].

In November 2014, eHealth Network also adopted the first Guidelines for ePrescriptions [11]. The development of electronic instruments in this field will help harmonize practices and facilitate patient mobility, provided that the security and privacy of patient data are ensured [15, 16, 29].

In order to apply the European provisions to the Romanian national legislation, the following measures were taken: Law no. 95/2006 on healthcare reform was completed with Title XIX - Cross-border healthcare [21]; while Government Ordinance no. 304/2014 for the approval of methodological norms on cross-border healthcare [12], and Joint Order no 340/214/2014 of the Minister of Health Care and the President of the National Health Insurance House concerning the approval of the National Contact Point for cross-border healthcare were

adopted [18]. Moreover, in order to include all the elements stipulated in Directive 2012/52/EU, the form of electronic prescriptions reimbursed by the national health insurance system was amended following the approval of Joint Order no. 674/252/2012 of the Minister of Health Care and the President of the National Health Insurance House [19].

It has become clear that, given the increase in patient mobility in Europe, community pharmacists from any EU Member State are likely to increasingly find themselves in the following cross-border healthcare situations: conational patient with medical prescription issued in another Member State, or patient from another Member State with prescription issued either in the Member State of the pharmacist or in another Member State. At the same time, regardless of situation, pharmacists from European countries have the professional obligation to provide quality services in accordance to national standards, as this field has not been the object of EU harmonizing policies. In Romania, pharmacy quality standards are included in the Order of the Minister of Health no. 75/2010 for the approval of good pharmacy practices rules [20]. In order to facilitate the application of good pharmacy practice rules, the Romanian College of Pharmacists created models of standard operating procedures for pharmacy activities [13], as well as procedures for the evaluation of pharmacists, approved by Decision no. 1/2011 [3], which monitors the quality of community pharmacy activities [14, 30]. In its capacity of competent authority at national level, the professional association has to consider the international trends in the field, which are reflected in the 2011 Joint FIP/WHO Guidelines on Good Pharmacy Practice, advocating the creation of national quality standards for pharmacy services according to the needs and aspirations of the profession [33].

The paper aims to analyse the impact of European provisions regarding cross-border healthcare on pharmacy activities as far as the dispensing of prescription medication is concerned, given the fact that pharmacists must conform to the requirements of good pharmacy practice in order to ensure the patients' right to quality products and services. Based on this analysis, measures aimed at facilitating the implementation of European provisions on the cross-border recognition of prescriptions shall be proposed.

### Materials and Methods

The comparative method [6] and methods of interpretation [8] were used to study the European provisions included in Directive 2011/24/EU, Directive 2012/52/EU, and the Guidelines for ePrescriptions concerning the cross-border recognition of prescriptions

including medicinal products. The provisions of the 2011 Joint FIP/WHO Guidelines and the Order of the Minister of Health no. 75/2010 regarding the dispensing of prescription medication were also included in the analysis. The quality standards for appropriate pharmacy care constituted the analysis criteria used in this research, in accordance to the following good practice standards: the assurance of the required human and material resources, as well as the standard operating procedures for the dispensing of prescription medication; the verification of the authenticity and legality of prescriptions; the thorough evaluation of prescriptions; the dispensing of medication, following correct patient information and counselling, in order to obtain maximum treatment benefits [3, 20, 33].

## Results and Discussion

### *The assurance of the required human and material resources, and the standard operating procedures for dispensing of cross-border prescriptions*

According to Directive 2011/24/EU, cross-border prescriptions must be recognized and honoured without restrictions and discrimination [7], which means that the dispensing of such prescriptions cannot be refused unless they were also refused in a non-cross-border context.

To this end, the assurance of the human resources required for quality, efficient and safe dispensing of medication [3, 20, 33] in cross-border healthcare requires the appropriate training of pharmacists in the following fields: national and European legislation on cross-border healthcare, specific procedures (contact with national contact points for cross-border healthcare, contact with professionals from other Member States, receiving and evaluating cross-border prescriptions, good practices for managing electronic databases [11], etc.), instruments (paper or electronic cross-border prescriptions, databases of prescribing health professionals and/or health care units from other Member States, health insurance cards and electronic patient records, etc.), and international languages. Therefore, professional associations should offer pharmacists training courses recognized and accredited by existing national programs for continuing pharmacy education in these fields.

The assurance of the material resources required for quality, efficient and safe dispensing of medication [3, 20, 33] in cross-border healthcare requires that pharmacies are connected to the Internet, or, if needed, they should be equipped with devices for managing electronic prescriptions, electronic health insurance cards and electronic patient records. Systems operating in different European states should be compatible so that electronic prescriptions, electronic health insurance cards and electronic

patient records can be used successfully. A first step in this direction was the creation of Guidelines for ePrescriptions, which, although not mandatory, can help Member States develop the interoperability of electronic prescriptions, if these are to be implemented at national level [11].

In order to ensure standardized practice [3, 20, 33] in the dispensing of cross-border prescriptions, special national procedures can be created with the support of professional associations, or alternatively, the general procedure for dispensing prescriptions can be completed with specific rules for cross-border prescriptions. If the Guidelines for ePrescriptions are implemented at the national level, the procedure for dispensing cross-border prescriptions must include not only the specific rules for managing cross-border electronic prescriptions, but also those referring to the verification of patient identity and status: the verification of the European health insurance card and of the photo ID [11], which require the appropriate training of pharmacists.

### *The verification of the authenticity and legality of prescriptions*

The authenticity of both paper and electronic prescriptions is confirmed following the evaluation of an original form issued by a certified healthcare professional working in a clinic, hospital, doctor's office, etc. The following represent specific identification elements: a stamp with the name and signature of the prescribing health professional, respectively, possibly, a stamp with the name of the public health care unit of the prescribing health professional in the case of paper prescriptions; an electronic signature, or an extended electronic signature, respectively, in the case of electronic prescriptions [3, 19, 20]. Of all these, only the signature of the prescribing health professional is required by Directive 2012/52/EU [5]. The measures that could facilitate the authentication of cross-border prescriptions include: the creation of a specific form for cross-border prescriptions in paper or electronic format containing specific identification elements, or the creation of easily accessible Internet-based national and European updatable databases containing the prescribing health professionals of each Member State (first name and surname, title, right to prescribe according to category: specialist doctors, dentists, veterinarian doctors, midwives, etc.) and the health care units that these categories are affiliated to (name, address, authorized activities). Until such databases are created, pharmacists can contact the national contact point for cross-border healthcare of the care-providing Member State in order to identify the status of the prescribing health professional and of its health care unit. In this case, sufficient knowledge of an international language is required for successful

communication. According to Directive 2011/24/EU [7], pharmacists can refuse to dispense a medical prescription if they have legitimate and justified doubts regarding its authenticity.

Guidelines for ePrescriptions propose a very complex form for cross-border prescriptions, which contains authentication elements, a prescription ID, a unique identification number, and a traceability code, which allows the authentication of the prescription. Cross-border prescriptions also include, besides the electronic signature of the prescribing health professional, a health care provider identifier (HCPI), which is a unique identification code of the prescribing health professional [11]. We consider that the issue date of the prescription, regarded as an authentication element by both Directive 2012/52/EU [5], and the Guidelines for ePrescriptions [11] represents a technical element that only provides the pharmacist with information on the validity of the prescription.

The legality of the prescription is first of all demonstrated by the existence of an adequate form for the prescribed medication. However, given the fact that cross-border prescriptions are not reimbursed in the state of treatment, and that the principle for recognizing cross-border prescriptions is not applicable to medicinal products subject to special medical prescription such as narcotics or psychotropic drugs [7], the form for paper cross-border prescriptions is simple and lacks the specific elements required in these two situations, which are subject to different national regulations in each Member State. Nevertheless, the Guidelines for ePrescriptions suggest the introduction of a very complex, specific and appropriate form for electronic prescriptions in such situations [11].

Secondly, the legality of the prescription is proven by the integral and correct completion of all form rubrics by the prescribing health professional. Therefore, the use of a common language for cross-border prescriptions would be useful. An alternative could be the introduction of bilingual forms in which the first language is that of the state of treatment, followed by an international language. As far as the content of the form rubrics is concerned, prescriptions contain useful information on the health care unit, the prescribing health professional, the date of issue, the patient and the prescribed treatment. A cross-border prescription form should contain rubrics referring to: the health care unit - name, address, city, state; the prescribing health professional - surname, first name, professional qualification, contact details for easier professional contact (e-mail, telephone and fax number); the patient - surname, first name, age, gender, weight, diagnosis; prescribed medication - name, pharmaceutical formulation, strength, quantity, dosage regimen, duration of treatment; other recommendations -

cosmetic and hygienic products, dietary supplements, other products. Directive 2012/52/EU stipulates that most of the above-mentioned elements must be included in cross-border prescriptions [5], except for the name of the health care unit, patient gender and weight, diagnosis, duration of treatment and other recommendations.

While information on the health care unit may be obtained from the Internet database or from the national contact point, the other information regarding the patient and the prescribed treatment is necessary so that pharmacists can correctly evaluate the prescription and the patient's needs according to good pharmacy practice [3, 20, 33]. Therefore, we consider that these should not be excluded from cross-border prescription forms. In fact, according to the Guidelines for ePrescriptions, the rubrics for electronic cross-border prescriptions include this information, although some are optional. On the other hand, additional rubrics asking for patient details such as height, allergies or health problems were also added [11], turning the form into a mini patient record in order for dispensing pharmacists to better understand the patient's situation.

Electronic prescriptions represent the best solution for avoiding issues generated by the handwriting of the prescribing health professional. However, if electronic prescriptions contain missing or unclear information, direct contact with the prescribing health professional is required. In such situations, sufficient knowledge of an international language is needed for successful communication.

According to Directive 2011/24/EU [7], pharmacists can refuse to dispense a prescription if they have legitimate and justified doubts regarding the content or accuracy of the prescription.

#### *The thorough evaluation of prescriptions*

Pharmacists must evaluate cross-border prescriptions. This requires: the correct identification of medication, the therapeutic evaluation of the prescription (dosage regimen, indications, etc.), the analysis of the risks associated with dispensing medication (contraindications, adverse reactions, precautions, interactions, etc.), economic aspects (the price of medicinal products), some social aspects (the patient's social situation – educational level, occupation, income, etc.) or legal issues (the original form of paper prescriptions is retained or not at the pharmacy, according to the legal status of the dispensed products in the respective country) [3, 20, 33]. The measures capable of facilitating the evaluation of cross-border prescriptions include the use of electronic prescriptions, for avoiding issues related with handwriting comprehension, as well as the possibility of easy contact with the prescribing health professional in case of missing or unclear information. The correct identification of medicinal products is crucial for quality professional

practice. In this respect, Directive 2011/24/EU stipulates the use of common international names in prescriptions, while Directive 2012/52/EU establishes that the common names of medicines should be used in prescriptions, except for the prescribing of brand names only accompanied by the medical reasons justifying it, or the prescribing of biological medicinal products, respectively [5].

However, the brand name may not be sufficient sometimes [25]. Such cases require the use of electronic instruments and new practices for ensuring the safe identification of medicinal products prescribed in a state and their safe substitution in a different state, where the products are dispensed [11, 29]. We believe that for now, the contact with the prescribing health professional is necessary whenever the name of a medicinal product does not allow the safe identification of the active substance(s) needed by the patient. According to the Guidelines for ePrescriptions, the use of electronic prescriptions could facilitate the identification and correct substitution of medicinal products in cross-border prescriptions, while a more in-depth approach to the problem of generic and therapeutic substitution is envisaged for the next version of the guidelines [11].

After the correct identification of the active substance(s), the pharmacist must allow the patient to make an informed decision and choose a synonymous drug available in the pharmacy. The identification of a common language for discussion is required for the appropriate patient-pharmacist communication required in order for the prescription to be correctly evaluated, relevant information on the available medicinal products to be provided so that patients can make the best decision, as well as for supplying information and counselling when dispensing medication. In fact, according to the Guidelines for ePrescriptions, one of the rubrics in cross-border prescriptions refers to the patient's first language [11], since this information can be useful for the pharmacist when evaluating the prescription, dispensing the products and counselling the patient.

According to Directive 2011/24/EU [7], pharmacists can refuse to dispense a prescription if they have legitimate and justified doubts regarding its content or accuracy. Pharmacists can also refuse to dispense a cross-border prescription because of ethical reasons [7], such as when considering, following the evaluation of the prescription and of the patient's condition, that the prescribed medication is not in the best interest of the patient's health, according to the Romanian Deontological Code of Pharmacists [4]. In such cases, the reasons behind this refusal must be clearly stated. They should also be the same reasons invoked in the case of a non-cross-border prescription.

#### *The dispensing of medication following correct patient information and counselling*

After identifying and selecting the medicinal products listed in cross-border prescriptions, pharmacists must dispense the respective products as well as provide quality information and counselling to the patient, who should receive sufficient comprehensible written information and adequate counselling in order to gain maximum treatment benefits [3, 20, 33]. In order for this to happen, pharmacists need to know the patient's situation (health issues, education, status, etc.); they must be able to provide written information on the prescribed medication (patient information leaflet, dosage regimens, other recommendations, etc.), as well as patient counselling (specific indications, contraindications, adverse reactions, interactions, hygiene or dietary habits, etc.). These should be adapted to the patient's situation so that treatment can be carried out appropriately. Pharmacists' access to all the necessary information regarding the patients' health status, for the correct evaluation in the context of their medical and medicinal history, would represent one measure aimed at facilitating patient counselling in cross-border situations. The use of the cross-border electronic prescription form proposed in the Guidelines for ePrescriptions, which includes rubrics on the patient's health status [11], could be a first step in this direction.

Regardless of whether pharmacists have access to the patient's medical records, or if information is obtained following direct patient interviewing, a common language of communication for adequate patient information and counselling is needed.

In cases when no common language for communicating with patients is identified, standard procedures such as contacting the national contact point for cross-border healthcare, or the previous identification and localization of foreign language speaking pharmacists should be implemented in order to provide patients with quality solutions as far as the dispensing of medication is concerned.

Providing written information to the patient, as package leaflet, can be relatively simple for medicines authorized at EU level through centralized procedure, since these are available for printing on the website of the European Medicines Agency in the languages of all Member States. On the other hand, providing information on medicines authorized through decentralized or national procedures may prove problematic if the respective medicinal products had not been authorized in the Member State of the patient, because the pharmacist cannot offer detailed written information in the patient's language. However, both patient management during treatment and the evaluation of patient results and progress [3, 20, 33] will be the task of a pharmacist from the Member State of the patient. In such cases, the pharmacist should communicate with the pharmacist

from the Member State of treatment in order to provide the continued care of patients.

Keeping a record of dispensed medication for verification at a later date is another duty that pharmacists have [3, 20].

In cross-border healthcare, pharmacists must provide patients with the documents required for the reimbursement of medication in their Member State of affiliation, where applicable: copy of the paper prescription and proof of payment of the dispensed medication [12], according to the national regulations of the patient's Member State of affiliation.

## Conclusions

According to Directive 2011/24/EU, the general principle of cross-border healthcare is the opening, for European citizens, of the possibility of choosing health care providers and of being reimbursed for medical services and medication prescribed or dispensed in a Member State other than that of affiliation. The recognition of cross-border prescriptions, facilitated by the common elements stipulated in Directive 2012/52/EU, represents another principle of cross-border healthcare. Rules for the implementation of electronic prescriptions and for the development of their interoperability in Member States were proposed in the Guidelines for ePrescriptions.

The implementation of the principle of recognizing cross-border prescriptions represents a new challenge for pharmacists, who have to: use new instruments and procedures for managing cross-border prescriptions, established through implementation measures at European and national level; dispense medicinal products prescribed by professionals from other Member States; cooperate with professionals from other Member States in the best interest of the patient; and provide quality pharmacy services according to the standards of good pharmacy practice, regardless of the origin of the patient or of the prescription. Although the implementation of electronic prescriptions and of the system of interoperability would require important human and material resources, it would also facilitate the safe and quality dispensing of cross-border prescriptions. The national professional associations of pharmacists could have an important role in facilitating the implementation of these new rules of practice, especially through the coordination of lifelong training programs for pharmacists, as well as through the creation of adequate procedures for managing cross-border healthcare activities.

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