

REGULATORY GUIDANCE

Dispensing Prescriptions issued by EEA doctors and dentists

Revised December 2010 (Controlled Drugs)



Dispensing Prescriptions issued by doctors and dentists in the European Economic Area (EEA) or Switzerland

Since 3rd November 2008, pharmacists in the UK have been able to dispense a prescription issued by a doctor or dentist registered in an EEA country or Switzerland. This is enabled by *The Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008* and is designed to assist patients in continuing to access treatment and care should this be necessary whilst they are visiting or working in the United Kingdom.

However, this change in law does not *require* the pharmacist to dispense such prescriptions. Pharmacists must exercise their professional judgement and due diligence in deciding whether to dispense a prescription or not (See sections 8 and 9 of guidance below).

The Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008 only apply to prescriptions written by EEA or Swiss dentists or doctors, and no other prescribers. Consequently, prescriptions issued by a nurse or pharmacist in another EU state cannot be accepted for dispensing in a registered pharmacy in the UK.

1. Prescription Requirements

The legislation defines some minimum standards that an EEA prescription must comply with in order to be dispensed. These are:

- The prescription originates in EEA state (excluding the UK) or originates in Switzerland.
- It is signed in ink with the name of the prescribing EEA / Swiss doctor or dentist.

- The rest of the prescription is written in ink or otherwise indelible and includes:
 1. The address of the EEA / Swiss doctor or dentist
 2. The date the prescription was signed by the EEA / Swiss doctor or dentist
 3. The qualification of the EEA or Swiss doctor or dentist
 4. The name of the person for whose treatment it is given.

From 26 July 2010¹, it is **no longer** a legal requirement that a prescription issued by an EEA doctor or dentist must include the following details in order to be dispensed in the UK:

- The address of the patient listed on the prescription; or,
- The age of the patient listed on the prescription, if less than 12 years old.

The reason for this change is that, although these **remain** legal requirements to dispense prescriptions issued by UK prescribers, not every EEA state operates similarly. The previous requirement² was therefore judged by the European Commission to unfairly exclude many EEA patients, in possession of a prescription written by a doctor or dentist in their home country, from receiving their medications whilst visiting or working in the UK.

Guidance to pharmacists on maintaining good clinical governance when dispensing against a prescription issued by an EEA Doctor or Dentist -

Having access to information about a patient's age assists pharmacists in assessing the risk profile posed by a medication and its appropriateness, on an individual basis.

Establishing the local address of the patient provides a means of:

- Ensuring that the assembled medication is supplied to the correct person; and,
- Contacting the patient after supply if necessary for clinical purposes.

¹ See The Medicines for Human Use (Prescribing by EEA Practitioners) (Amendment) Regulations 2010 http://www.opsi.gov.uk/si/si2010/uksi_20101673_en_1

² That a prescription issued by a doctor or dentist in another EEA state must include the age and address of a patient in order to be dispensed in the UK

Therefore, on receipt of an EEA prescription without such information, the pharmacist should, in all cases:

- Seek to ascertain the age of any patient under the age of 12; and,
- Request the local address of the patient and annotate the prescription accordingly.

As with UK prescriptions, the prescription is **valid for 6 months** from the date on which it was signed.

2. Repeat Prescriptions issued by EEA Doctors and Dentists

It is also permissible for UK pharmacists to dispense medications on a repeat basis, on presentation of a prescription issued by an EEA doctor or dentist. This should be conducted under the same conditions as prescriptions written by UK prescribers that is:

- The first dispensing should be made within 6 months of the date on which it was signed;
- The dispensing instructions of the prescribing EEA / Swiss doctor or dentist are followed.

If the number of repeats is not stated, then the prescription can only be repeated once i.e. a maximum of two supplies on the prescription – the only exception is a prescription for a contraceptive which can be repeated up to six times up to **6 months** from the date the prescription was first signed.

3. Prescriptions issued by EEA³ doctors and dentists and Controlled Drugs

On the 20 December 2010 further amendments to *The Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008* came into force in relation to Controlled Drugs and prescriptions issued by EEA doctors and dentists.

It remains the case that pharmacists in Northern Ireland may **not** dispense prescriptions for Schedules 1, 2 & 3 Controlled Drugs on the basis of a prescription issued by an EEA doctor or dentist.

However, the amended regulations **do** now permit pharmacists to dispense prescriptions issued by EEA doctors and dentists for Schedule 4 and 5 Controlled Drugs.

A related change has also been made to the regulation on the emergency sale or supply of Controlled Drugs (Schedule 4 and 5) to an EEA or Swiss national. See Section 7 of this guidance below.

It should be noted that these changes do not effect how Controlled Drugs are regulated more generally within pharmacy. The dispensing of any Controlled Drug against a prescription must continue to be subject to the professional judgement of the pharmacist and the pharmacist must observe due diligence in ensuring that an EEA prescription for a Schedule 4 or 5 Controlled Drug is both legally issued and clinically appropriate for the patient.

A current list of Controlled Drugs and MDA schedules is available from the Home Office website here:

<http://www.homeoffice.gov.uk/publications/drugs/drug-licences/controlled-drugs-list?view=Binary>

³ EEA doctors and dentists referenced here will not be registered with the General Medical Council in the United Kingdom

4. Medicines with no UK marketing authorisation

The Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008 do not extend to the prescribing of medicines which do not have a marketing authorisation in the UK. Pharmacists cannot dispense prescriptions for drugs with no Marketing Authorisation in the UK.

5. Substitution of product

If a doctor or dentist from the EEA or Switzerland has written a prescription for a named branded medicine, a pharmacist may only dispense the brand named on the prescription – a pharmacist may **not** dispense a UK equivalent.

It should be noted that this requirement is the same for prescriptions issued by UK prescribers. By way of example, if a doctor has written a prescription for Zestril® - a pharmacist can not give another brand of Lisinopril in its place.

Occasionally a pharmacist may find that the generic names of medicines in Europe are different from the names in the UK, although generally speaking the generic names for medicines in other EEA countries are the same or similar to the generic names used in the UK.

6. Charges for Prescriptions

The EEA prescriptions presented to pharmacists will not be NHS prescriptions, so they should be treated in the same way as private prescriptions within the UK with appropriate checks and records made. The charges levied to the patient are a matter for the individual pharmacist.

7. Emergency Supplies at the request of a doctor or dentist in the EEA

The Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008 permit a UK pharmacist to make an emergency supply at the request of a doctor or dentist from an EEA country or Switzerland, and also at the request of a patient who has previously been prescribed a particular medicine by an EEA or Swiss doctor or dentist.

For example, if a patient from Poland requested an emergency supply for insulin (which they had forgotten to bring with them on their weekend trip) a pharmacist can legally make an emergency supply. A pharmacist should remember to make all appropriate records and follow the same procedure that they would for any other patient.

Conversely, if a doctor or dentist from an EEA country or Switzerland contacts your pharmacy and requests an emergency supply, a pharmacist should follow standard process for dealing with emergency supplies. It may be pertinent to remind the doctor/dentist that they must furnish a prescription within 72 hours.

No emergency supply of schedules 1, 2, and 3 Controlled Drugs can be made by a pharmacist on the basis of non-UK EEA prescription. Pharmacists should observe due diligence in making any decision to make an emergency supply of a schedule 4 or schedule 5 controlled drug on the request of a doctor or a patient. Appropriate records should be kept of any emergency supply.

8. Dispensing a Prescription Originating from the EEA (and Switzerland)

With the dispensing of any prescription the pharmacist must exercise their professional judgement on whether to dispense the prescription or not. Decisions reached should involve due diligence and ensure that a patient is not put at risk by the decision to either supply, or not to. The pharmacist must satisfy themselves that:

- The prescription is not fraudulent
- The prescription meets the requirements of the regulations (see above)
- The prescription is clinically appropriate for the patient
- In the case of an emergency supply that:
 - The request of the doctor/ dentist is genuine;
 - The request of the patient is genuine.

9. Not Dispensing a Prescription issued by an EEA doctor or dentist

In choosing not to dispense a prescription, the pharmacist must exercise their professional judgement. Any decision must be made in the best interests of the patient. If you are in any doubt about what is being prescribed you must exercise caution.

It is good practice to record the reason for any decision not to dispense. For example, the pharmacist was not able to contact the prescriber or the pharmacist was not satisfied the patient was previously prescribed the medication.

10. Standard Operating Procedures

All pharmacies should consider if revision of Pharmacy Procedures is required in respect of these regulations, particularly those procedures legally mandated by the Responsible Pharmacist Regulations⁴.

This may be particularly significant in areas of Northern Ireland where there is likely to be traffic of prescriptions from doctors and dentists registered in the Republic of Ireland.

11. Checking a prescription with a prescriber in the EEA

In order to check a prescription with an EEA prescriber a pharmacist may need to contact a registering body of medics or dentists in another EEA country in order to gain the prescriber's contact details.

The General Medical Council (GMC) has a document on its website which details the contact details for the equivalent competent authority within the EEA.

http://www.gmc-uk.org/doctors/registration_applications/evidence_of_qualifications.asp

The General Dental Council (GDC) also hosts a useful document on its website containing the contact details for the equivalent competent authorities within the EEA. This can be accessed using the link below.

www.gdc-uk.org/Current+registrant/Working+in+another+EEA+member+state.htm

12. Further contact points

If you require further clarification on the requirements of these new regulations do not hesitate to contact the Pharmaceutical Society of Northern Ireland.

Email: info@psni.org.uk

Tel: 02890 326 927

⁴ See Pharmaceutical Society of Northern Ireland's Professional Standards and Guidance on the Responsible Pharmacist Regulations: http://www.psni.org.uk/documents/352/Standards+on+the+Responsible+Pharm_.pdf

This Guidance was originally published in November 2008 following the enactment of The Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008.

The Guidance was updated in July 2010 in respect of amendments to the regulations which no longer required prescriptions issued by an EEA doctor or dentist to detail the address and date of birth (if under 12) of the patient in order to be dispensed in the UK.

The Guidance was further updated in December 2010 in respect of amendments to the regulations permitting UK pharmacists to dispense Schedules 4 & 5 Controlled Drugs against a prescription issued by an EEA pharmacist, and to make emergency supplies of such medicines to patients from other EEA states.

Annex A – List of EEA Countries

Austria	France	Liechtenstein (*)	Romania
Belgium	Germany	Lithuania	Slovakia
Bulgaria	Greece	Luxembourg	Slovenia
Cyprus	Hungary	Malta	Spain
Czech Republic	Iceland (*)	Netherlands	Sweden
Denmark	Ireland	Norway (*)	United Kingdom
Estonia	Italy	Poland	
Finland	Latvia	Portugal	

(*) These countries are not present members of the European Union (EU) (July 2010).

Switzerland is also included within the scope of the Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008.