NHS European Office

European Commission consultation on measures for improving the recognition of medical prescriptions issued in another member state

NHS European Office response

The National Health Service (NHS) is one of the largest publicly funded healthcare systems in the world, providing the majority of healthcare in the UK. The NHS is committed to the principle of universal access to healthcare which is free at the point of use. Every 36 hours the NHS sees over one million patients who make use of a wide range of health services ranging from primary care, in-patient care, long-term healthcare, ophthalmology and dentistry. The NHS is also the largest employer in Europe with more than 1.5 million people on its payroll.

This response has been coordinated by the NHS European Office in consultation with NHS pharmacists and other health professionals in England.

Issues in the recognition of cross-border prescriptions

1 - a) Problems in the recognition of cross-border prescriptions for dispensers

Please score the below potential issues with
1 = least likely to cause problems, 9 = sure to cause problems

Authenticating the legitimacy of the prescription	**9**
Authenticating the entitlement of the prescriber	**8**
Understanding the language the prescription was written in	**7**
Understanding prescriptions that are hand-written	**7**
Dispensers having insufficient information on the prescription for their national (legal) requirements	**5**
The prescribed drug and/or device not being available on the local (national) market	**6**
In case substitution is possible: no suitable alternative drug or device being available on the local (national) market	**6**

1 - b) which other elements could cause problems in the dispensing of cross-border prescriptions?

The list above covers several potential issues, but we have been alerted to others that may cause problems in the dispensing of cross-border prescriptions. These are:

- language issues between the pharmacist and patient, which may prevent the pharmacist explaining about medicines or why a prescription cannot be dispensed.
- differences in licensed doses and indications in different countries.
- the differing status of medicines in different countries (e.g. prescription-only medicines (POMs), pharmacy (P) medicines, and general sales list (GSL) medicines) and how to be aware of this. The same product can also be classified as a medicine in one country and a medical device in another.
- a lack of information systems. For example, websites giving details of registered prescribers/physicians (where available) are normally only in the language of the home Member State and hence difficult to navigate. Similarly, there is often little or no access to reliable sources of information on EU medicines for dispensers.

Identifying the prescribed product

2 - a) Which elements in prescription forms contribute to the identification of medicinal products?

Please score the below potential issues with
1 = least important, 9 = most important

International Non-proprietary Name (INN) / generic name	**9**
Brand name	**5**
Form of administration	**7**
Quantity	**4**
Strength	**7**
Dosage regimen or direction for use	**7**
Intended duration of use	**6**

2 - b) which other elements could contribute to a better identifying the medicinal product?

In terms of identifying the medicinal product, if all prescriptions are written in INN it should be possible to define the item prescribed. This may not be possible though where script is written in a different alphabet, e.g. in Greece, and commas and decimal points also have a different meaning in different European countries.

Once the validity of a prescription has been established, a common problem is that the product, formulation or strength of medicine prescribed is not actually available in the UK. There is therefore the need for a common guide for prescribing (when dispensing is expected to take place outside the prescriber's Member State) and to aid with dispensing. In the UK for example, the Martindale Drug Reference guide is commonly used to provide reliable and evaluated information on drugs and medicines used throughout the world. Similarly there could be a role for a European equivalent of the British National Formulary, that lists the most common medicines (for example, those for chronic diseases) and their availability in different forms and strengths across EU Member States.

2 - c) which elements in prescription forms contribute to the identification of medical devices?

Please score the below potential issues with
1 = least important, 9 = most important

Generic name	**7**
Brand name	**7**
Product type	**8**
Directions for use	**7**
Quantity	**5**

2 - d) which other elements could contribute to a better identifying a prescribed medicinal device?

There may be a problem if the same item is licensed as a medicine in one country and a medical device in another. An increasing number of single dose eye drops, for example, are being licensed as medical devices, so are not licensed medicines and no information is available in the British National Formulary. The difficulties this causes will be further compounded if the prescription is in a foreign

language.

Identifying the patient

3 - a) which elements in prescriptions contribute to the identification of the patient?

Please score the below potential issues with
1 = least important, 9 = most important

Surname	**9**
First name(s) or initials	**9**
Gender	**6**
Date of birth	**9**
Home address	**8**

3 - b) which other elements could contribute to a better identification of the patient?

Those listed above are all important measures of identification, though additional forms would certainly help. These could include an NHS number or equivalent in other countries, if one such exists – which would also confirm eligibility to receive reciprocal care; and the patient's passport and/or their European Health Insurance Card (EHIC), which could also be used to confirm country of origin as well as eligibility.

Improving patient understanding of prescriptions

4 - a) which elements in prescription forms contribute to a better patient understanding of what is prescribed?

Please score the below potential issues with
1 = least important, 9 = most important

Wording of dosage (written out in full, use of non-Latin terms, etc)	**8**
Use of icons (representing what time to take the medicine)	**5**
Length of treatment	**6**
Instructions for proper use (e.g. 'take with food' etc)	**9**
Print prescriptions (instead of handwriting)	**9**

4 - b) which other elements could contribute to a better understanding of what is prescribed?

It is worth noting that the prescription form itself primarily acts as an instruction to the pharmacist, and we would look to the subsequent labelling on whatever has been prescribed as a suitable location for clear information to be provided to the patient.

Focusing on the interaction between the patient and the pharmacist, if the prescription is written in a language other than the native language of the patient, or the person dispensing it, it may be difficult to ensure directions for taking and other patient information is understood.

Simple information leaflets or medication cards and electronic access to national formularies for patients may therefore help provide pharmacists with a valuable resource to provide cross-border patients with written information in their chosen language.

Identifying the prescriber

5 - a) what are the main reasons to have clear prescriber identification in prescription forms (minimum of one choice)?

To verify the legal entitlement of an individual to prescribe in his/her Member State ('prescriber authentication')	**Yes**
To enable contact between dispenser (pharmacist, etc) and prescriber (physician, etc) to allow for a better understanding of the prescriptions (e.g. to understand unclear handwriting)	**Yes**
Other (please explain)	**The latter reason is also important in enabling discussions on potentially unsafe or inappropriate prescriptions with the prescriber and in deterring criminal activity related to medicines**

5 - b) how can prescriber authentication best be guaranteed?

Please score the below potential issues with
1 = least best solution, 9 = best solution

Paper solutions using elements in prescriptions to identify the prescriber such as name, address, qualification, prescriber code, etc	**5**
Paper solutions using elements in prescriptions to 1) identify the prescriber such as name, address, qualification, prescriber code, etc AND 2) enable contact with the prescriber such as phone/fax number, email, etc	**6**
National prescriber database accessible to dispensers (e.g. via internet) using information on the prescription as a starting point	**7**
An EU-level prescriber database accessible to dispensers (e.g. via internet) using information on the prescription as a starting point	**8**
A paperless e-prescription solution, e.g. allowing dispensers to verify information in a central repository on prescriber, prescription and patient	**8**

5 - c) which other solutions could improve prescriber authentication?

To guarantee fully prescriber identity would, in all probability, require an electronic EU wide database, linked to unique identifiers or registration numbers. This may though be difficult to establish in the near future and, given the relatively low numbers of cross-border prescriptions in operation, prove disproportionate and expensive. A possible other solution would be to require Member States to have real-time web-based lists of registered professionals. These should be publicly searchable and representative of those fit to practise at any one time.

Paper solutions could also be open to falsification.

5 - d) which elements in prescription forms contribute to the identification of the prescriber?

Please score the below potential issues with
1 = least important, 9 = most important

Surname	**9**
First name(s) or initials	**8**
Professional qualification	**8**
Work address	**6**
Details for direct contact with prescriber (either telephone, fax or email)	**6**
Signature (written or digital)	**8**

5 - e) which other solutions could contribute to a better identification of the prescriber?

There must be a means of independent verification of prescriber authenticity, and preferably via an electronic database at an EU-level, or as discussed earlier and more realistically, at national level. Therefore the above are really only valid in conjunction with an online register of prescribers – which needs to include any conditions or restrictions on right to prescribe. The UK registers independent and supplementary prescribers and it is important that any future EU system implemented to support cross-border prescriptions recognises this group of prescribers. If such a database is not possible then the contact details of the prescriber's national regulator and their own professional registration number would be helpful information.

Other information

6 - a) which other information is necessary in prescriptions?

Please score the below potential issues with
1 = least important, 9 = most important

Indication for prescribing	**6**
Date of prescription	**9**
Period that prescription is valid for	**9**
Generic substitution possible (yes/no)?	**7**

6 - b) which other elements would you add?

The age of the patient is a legal requirement in UK for patients under 12 and normally provided for all patients. We would like to see this added. There is other data in the UK that is currently generally available only to secondary pharmacists and dispensers, sometimes via patient notes, which could also be helpful to primary care. This includes: - other medication which the patient is taking

- the patient's weight, in particular for paediatrics and elderly
- significant co-morbidities or conditions, e.g. renal function, pregnancy etc.

Any other comments

The key issues are the validity of the prescription – which requires the pharmacist to use professional judgement – and the availability of the product.

The pharmacist has to balance the professional requirement to do the best for the patient (who may be experiencing the stress of being ill or running out of necessary medication) against the strict legal requirements for accurate dispensing in the UK. If the necessary information to validate the prescription and prescriber is not easily available they will have no alternative but to refuse to dispense the prescription, with this having consequences for the patient.

The current low level of information available on medicines and prescribers means that for a prescription generated in one country to be safely dispensed in another would in theory require common language and formularies. More information therefore on the availability of common products, in differing strengths and forms, across the EU would lead to prescribers writing prescriptions that stand a much greater chance of being dispensed.

Other factors which need considering include:
- the various national legislation on the prescribing and dispensing of medicines across Europe. For example, we would not support enabling doctors or dentists from EEA Member States writing prescriptions that contain less than the current requirements in the UK.
- whether any subsequent policy would include prescriptions for controlled drugs and drugs liable to misuse, which would often be declined at present
- publishing more Information on reciprocal arrangements for different countries.