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Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

Registered Pharmacies

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Dear Colleague,

Private prescribing and requirements for prescriptions

A number of matters have come to the attention of the Pharmacy Inspectors concerning private prescribing and the legality of associated prescriptions. As such, I wanted to write to the profession to remind you of your responsibilities in this regard.

Requirements for prescriptions: general

The Human Medicines Regulations 2012 (HMR 2012) govern the circumstances in which medicinal products may be sold, supplied or administered.[1] Regulation 214 requires that prescription only medicines (POMs) are not to be sold or supplied unless in accordance with a prescription. Regulation 217 outlines the requirements for a prescription and you are reminded that a prescription **must**:

- be signed in ink by the appropriate practitioner giving it;
- be written so as to be indelible;
- contain the address of the appropriate practitioner and an indication of the type of appropriate practitioner;
- contain the appropriate date;
- contain the name and address of the person for whom treatment is given; and
- contain the age for persons under 12.

Requirements for prescriptions: approved country health professionals

On occasion, pharmacists may be asked to dispense prescriptions issued by prescribers outside of the UK. In such circumstances pharmacists must ensure that the prescription has been issued by an approved professional in an approved country. Previous advice has been issued in this regard and is available on the Department's website at: https://www.health-ni.gov.uk/sites/default/files/publications/health/Letter-approved-country-health-professionals.pdf

The particulars that are required for such prescriptions are set out in Regulation 218 of the HMR 2012. Pharmacists should note that such prescriptions have requirements in excess of those outlined above. Such prescriptions **must**:

[1] https://www.legislation.gov.uk/uksi/2012/1916/contents

- be signed in ink by the appropriate practitioner giving it;
- be written so as to be indelible;

In addition, the prescription **must contain:**

- the patient's surname, first names written out in full and date of birth;
- the issue date of the prescription;
- the prescriber's surname, first names written out in full, professional qualifications, contact details including work address, email address and telephone or fax number with the appropriate international prefix;
- the name of the country in which the prescriber works;
- details about the prescribed product, including where applicable the common name of the product, brand name if the prescribed product is a biological medicinal product, or the prescriber deems it medically necessary for that product to be dispensed and the prescriber's reasons justifying the use of the branded product; and
- where applicable details of the product including pharmaceutical formulation (tablet, solution, etc.), quantity, strength, and dosage regimen

Pharmacists cannot dispense a controlled drug, listed in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations (Northern Ireland) 2002, against a prescription issued by an approved country health professional.

Electronic Prescriptions – UK prescribers

The Medicines Regulatory Group (MRG) is aware that pharmacists are increasingly being asked to consider making supplies of medicines using electronic prescriptions. The HMR 2012 makes provision for electronic prescriptions in Regulation 219. Electronic prescriptions **must contain**;

- the address of the appropriate practitioner and an indication of the type of appropriate practitioner;
- the appropriate date;
- the name and address of the person for whom treatment is given; and
- the age for persons under 12.

In addition, the prescription **must be**:

- created in electronic form;
- signed with an advanced electronic signature; and
- sent to the person by whom it is dispensed as an electronic communication

'advanced electronic signature' is defined within Article 3(11) of Regulation (EU) No 910/2014 and must meet the following requirements:[2]

- it is uniquely linked to the signatory;
- it is capable of identifying the signatory;
- it is created using electronic signature creation data that the signatory can, with a high level of confidence, use under his sole control; and
- it is linked to the data signed therewith in such a way that any subsequent change in the data is detectable

[2] Regulation (EU) No 910/2014 of the European Parliament and of the Council on electronic identification and trust services for electronic transactions in the internal market

MRG is unable to advise on particular systems and whether they meet the requirements detailed above.

Pharmacists cannot dispense a controlled drug, listed in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations (Northern Ireland) 2002, against an electronic prescription.

Electronic Prescriptions – approved country health professionals

On occasion, pharmacists may be asked to dispense electronic prescriptions issued by prescribers outside of the UK. In such circumstances pharmacists must ensure that the prescription was issued by an approved professional in an approved country and that the legal requirements as set out in Regulation 219A of the HMR 2012 are met. Such prescriptions **must contain**:

- the patient's surname, first names written out in full and date of birth;
- the issue date of the prescription;
- the prescriber's surname, first names written out in full, professional qualifications, contact details including work address, email address and telephone or fax number with the appropriate international prefix;
- the name of the country in which the prescriber works;
- details about the prescribed product, including where applicable the common name of the product, brand name if the prescribed product is a biological medicinal product, or the prescriber deems it medically necessary for that product to be dispensed and the prescriber's reasons justifying the use of the branded product; and
- where applicable details of the product including pharmaceutical formulation (tablet, solution, etc.), quantity, strength, and dosage regimen

In addition, the prescription **must be**:

- created in electronic form;
- signed with an electronic signature; and
- sent to the person by whom it is dispensed as an electronic communication.

MRG is unable to advise on particular systems and whether they meet the requirements detailed above.

Pharmacists cannot dispense a controlled drug, listed in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations (Northern Ireland) 2002, against an electronic prescription issued by an approved country health professional.

Other Regulatory Bodies

Medical prescribers providing services to patients in Northern Ireland, irrespective of the prescriber or service location, may require registration with the Regulation and Quality Improvement Authority (RQIA). Pharmacists should ensure that prescribers and services are appropriately registered with respective authorities when satisfying themselves as to the legality of prescriptions. The list of services registered with RQIA is available at: Regulation and Quality Improvement Authority - Social & Healthcare Services Directory Northern Ireland | Regulation and Quality Improvement Authority (rqia.org.uk)

Validity of prescriptions

Prescriptions for POMs are generally valid for six months from the appropriate date.

In the case of a repeatable prescription, it must not be dispensed for the first time after the end of that six month period, and it must be dispensed in accordance with the directions contained in the prescription.

In the case of a repeatable prescription that does not specify the number of times it may be dispensed, it must not be dispensed on more than two occasions; or in the case of a prescription for an oral contraceptive, it is not dispensed on more than six occasions or after the end of the period of six months from the appropriate date.

Notwithstanding the information above, prescriptions for controlled drugs in Schedules 2, 3 and 4 are valid for 28 days from the appropriate date whilst those in Schedule 5 are valid for 6 months from the appropriate date.

Supplying Medicines on Prescription

Pharmacists are asked to consider any prescriptions presented to them, assure themselves of the legal basis upon which they are making any supplies of medicines and determine whether the prescription meets the requirements of applicable legislation. Pharmacists must at all times operate in accordance with professional guidelines and ensure the clinical appropriateness of any supplies they make.

Pharmacists may be requested to provide dispensing services to patients at a distance, for example by post, either as a routine service or as an isolated request. Where such supplies are made to patients outside of the United Kingdom, pharmacists **must** ensure that they are operating in accordance with the laws of the destination country.

A pharmacist's right to exercise their professional discretion and refuse to dispense a prescription remains unchanged and may be appropriate if;

- the prescription would not ordinarily be dispensed in the UK;
- there are doubts over the prescription authenticity;
- there are concerns regarding the clinical appropriateness of the medicine(s) for that patient;
- or, it would cause issues of health and safety.

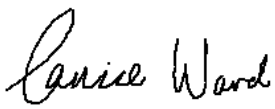
If a pharmacist chooses not to dispense a prescription they should, as a matter of good practice, record the reason for not doing so. If needed, patients should be signposted to appropriate services in circumstances where prescriptions cannot be dispensed.

If a supply is made pharmacists must adhere to statutory record keeping requirements and retention periods for prescriptions of this manner.

Conclusion

This letter sets out the general requirements pharmacists must take into account when considering supplying medicines from a variety of prescription types. The Medicines Regulatory Group cannot provide advice on the suitability of particular prescriptions or prescribing platforms and pharmacists may wish to obtain independent advice on this matter.

Yours sincerely,



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