



17th April 2020

Circular 015/20

Re: Changes in Medicines Legislation

Dear Doctor,

The Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2020 (S.I. No. 98 of 2020) and the Misuse of Drugs (Amendment) Regulations 2020 (S.I. No. 99 of 2020) were signed by the Minister for Health on the 3rd April 2020 allowing urgent temporary amendments to the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) and the Misuse of Drugs Regulations 2017 (as amended). The amendments were considered necessary in order to respond to the current COVID-19 emergency and will relieve some pressures on GPs and pharmacists to facilitate continuity of care.

The following FAQs have been developed to assist GPs in this regard.

Your co-operation and ongoing support is appreciated.

Yours faithfully,

Shaun Flanagan
Primary Care Reimbursement and Eligibility



GP Contractors Changes to Prescription Legislation Frequently Asked Questions

The Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2020 (S.I. No. 98 of 2020) and the Misuse of Drugs (Amendment) Regulations 2020 (S.I. No. 99 of 2020) were signed by the Minister for Health on the 3rd April 2020 allowing urgent temporary amendments to the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended) and the Misuse of Drugs Regulations 2017 (as amended). The amendments were considered necessary in order to respond to the current COVID-19 emergency and will relieve some pressures on GPs and pharmacists to facilitate continuity of care.

The following FAQs have been developed to assist GPs in this regard.

The HSE (www.hse.ie/coronavirus) and Health Protection Surveillance Centre (www.hpsc.ie) websites are updated on a regular basis for the most up to date COVID-19 information.

1. What is the period of validity for prescriptions?

The maximum period of validity of a prescription for a prescription only medicinal product (excluding Schedule 2 and 3 Controlled Drugs) is temporarily increased from 6 months to 9 months as of the date specified on the prescription. This amendment has been made for the period of the COVID-19 emergency to assist pharmacists and GPs.

Additional supplies may be made against prescriptions that had been dispensed in full prior to the COVID-19 Emergency Provisions.

The validity of prescriptions for Schedule 2 or 3 Controlled Drugs is unchanged i.e. a supply cannot be made later than 14 days after the date on the prescription. Validity for a Schedule 2 or 3 Controlled

Drug prescription to be dispensed in instalments is also unchanged i.e. the first instalment must be dispensed within 14 days of the date stated on the prescription and no instalment shall be supplied later than 2 months after the date specified on the prescription.

2. The amendments to the legislation allow for the electronic transfer of prescriptions.

What is the safe secure email system, Healthmail?

The amendments to the legislation remove the requirement for a paper copy of a prescription to be forwarded to a pharmacy as long as it is sent by the prescriber and received by the pharmacy via the closed-system electronic service, Healthmail, which is approved by the HSE.

Healthmail, secure clinical email, is a service that allows health care providers to send and receive clinical patient information in a secure manner. It is a valuable means of communication between prescribers and pharmacists in a timely manner around prescriptions and other clinical queries. A full directory of addresses is available in your Healthmail account by clicking on the People tab. Some hospitals and health care agencies are securely connected to Healthmail; a list of these is available at www.healthmail.ie.

Please ensure that you have the correct Healthmail address when transferring a prescription to the nominated pharmacy of the patient. Due care must be taken to ensure that the same prescription is not transferred more than once.

Further information and support for Healthmail can be found at <https://www.healthmail.ie/support.cfm>.

3. Are prescriptions sent via the National Electronic Prescription Transfer System required to have the prescriber's signature?

No - To meet the requirements for a legally valid prescription via the national electronic prescription transfer system, the prescription must:

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- be in an unalterable electronic form,
- be transmitted by the national electronic prescription transfer system,
- clearly indicate the date of issue,
- clearly indicate the professional registration number of the prescriber, and
- be traceable electronically back to the prescriber.

A prescription sent through Healthmail is traceable back to the prescriber and therefore a signature is not required on the prescription. The pharmacist must still be satisfied that in their professional judgement it is safe to make any supply in the context of the information received.

All other prescription requirements under the relevant legislation must still be met. There is no requirement for the signed paper prescription to follow at a later date.

Schedule 2, 3 and 4 Part 1 Controlled Drug prescription writing requirements still apply, however these do not need to be in the prescriber's own handwriting:

✓	Full name (including the first name) of Practitioner
✓	Practitioners' registration type and number (e.g. medical, dentist, veterinary etc.)
✓	Prescription date
✓	Except in the case of a health prescription, the prescription shall specify the address of the practitioner issuing it
✓	Telephone number of Practitioner
✓	Name (including the first name) and address of patient
✓	Name of Controlled Drug
✓	Dose, Form and Strength of Controlled Drug
✓	Total Quantity (in both words and figures) or the number (in both words and figures) of dosage units, as appropriate, to be supplied
✓	In the case of a prescription for a total quantity intended to be dispensed in instalments, the number of instalments and the intervals at which the instalments may be dispensed.

A prescription sent outside the national electronic prescription transfer system is not recognised in the legislation as a legally valid prescription. Depending on the software system, some prescribers will be able to send prescriptions directly from their prescribing module to Healthmail. If this is not possible the prescriber may print the prescription, scan it, and send it as an attachment via Healthmail.

4. What is the format for the prescription sent via Healthmail?

A prescription can appear in the following formats:

1. The prescriber scans and attaches the printed prescription to the Healthmail
2. The prescription is attached to the Healthmail in a typed-out format
3. The prescriber provides the prescription details in the main body of the Healthmail

It is permissible for the prescriber to submit prescriptions for those with GMS eligibility on plain A4 paper when submitted to the pharmacy via Healthmail. However, the prescriber should enter the valid GMS number of the patient to ensure seamless access to the medicines without charge.

Due care must be taken to ensure that the same prescription is not transferred more than once.

5. My GP practice has a generic Healthmail account, can I use this account to transfer prescriptions to the patient's pharmacy?

The legislation requires that prescriptions transferred via the national electronic prescription transfer system be traceable electronically back to the prescriber. Therefore, it is preferable from the dispensing pharmacy's perspective, if the prescriber has a Healthmail account specific to him/her. However, the professional registration number of the prescriber will suffice for the purposes of the new legislation if you are currently using a group practice healthmail account. If you have not done so already and wish to do so, you can register for a Healthmail account at www.healthmail.ie/.

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6. Is the patient GMS number still required on the prescription transferred to the pharmacy via Healthmail?

Yes – the valid GMS number for patients with full GMS eligibility must be on the prescription sent via Healthmail to the dispensing pharmacy for the patient to access their medicines without charge seamlessly.

7. Does a GMS prescription only allow for one month supply to the patient during the COVID-19 emergency period?

GMS standard prescriptions are not ordinarily endorsed to be repeated. However, the amended legislation permits S1A medicinal products ('non-renewable' products, for example; antidepressants, antipsychotics, hypnotics) to be dispensed on no more than four occasions where it is the opinion of the pharmacist that it is appropriate and necessary for the continued treatment of the person for further supplies to be made.

If the prescription does not state the number of occasions nor the intervals that the product may be supplied, S1B medicinal products ('renewable products' such as those for chronic conditions, for example; antihypertensives, lipid regulating drugs, asthma medication, drugs used in diabetes) may be supplied by the pharmacist for up to 9 months, on the number of occasions that the pharmacist deems appropriate, where it is in their opinion that it is appropriate and necessary for the continued treatment of the patient.

Furthermore, an original GMS prescription will be valid for ongoing supplies during the COVID-19 period. Where the pharmacist has an original GMS prescription for a patient, they can continue to use this prescription for further supplies as appropriate. These measures are in place in order to ensure continuity of patient care where it may not be feasible for a new prescription to be obtained.

Schedule 2 or 3 Controlled Drugs cannot be repeated. Prescriptions for Schedule 4 Controlled Drugs may only be repeated if specified by the prescriber.

8. Can I record 'Do not substitute' on the prescription transferred via Healthmail?

During the COVID 19 emergency, where the prescriber wishes the patient to access the proprietary product rather than the reference priced generic alternative, 'Do Not Substitute' can be computer generated on the prescription rather than in the prescriber's own handwriting.

9. Can I request an emergency supply of medication from a pharmacy for my patient?

Where a prescriber makes a request for an emergency supply for their patient, they must undertake to provide the prescription to the pharmacy **within 72 hours**. The National Electronic Prescription Transfer System will permit the transfer of a prescription between the prescriber and dispensing pharmacy by electronic means (i.e. Healthmail). Prescriptions sent through personal or commercial email accounts or fax are deemed as an emergency supply at the request of the prescriber. The original prescription must be provided to the pharmacy within 72 hours as a physical prescription or can be transferred via Healthmail.

At this time, a pharmacist is permitted to supply a Schedule 2, 3 or 4 Controlled Drug at the request of a prescriber where:

- it is unreasonable at the time of supply, in the circumstances arising from the COVID-19 emergency, for the person to obtain a new prescription for that medicinal product,
- it is in the opinion of the pharmacist that it is safe, appropriate and necessary for the continued treatment of the person for an emergency supply to be made, and
- no greater quantity of the product than will provide **5 days' treatment** is supplied.

A prescriber can also request 10 days emergency supply in the circumstances arising from the COVID-19 emergency of the following Schedule 4 Part 1 Controlled Drugs - midazolam, clobazam and clonazepam for the treatment of epilepsy.

10. Will a mental health services prescription be accepted under the GMS scheme during the COVID-19 emergency or will GPs be required to transcribe these?

Mental health services prescriptions will be accepted for reimbursement and will not require GP transcribing to a GMS Prescription Form. The original mental health services prescription or a prescription transferred via Healthmail is acceptable.

Furthermore, arrangements have been made to enable a full month's supply to be dispensed on a hospital prescription (where specified on the hospital prescription) under the Hospital Emergency Scheme where previously only seven day's supply was available.

11. I am a Level 1 /Level 2 GP, can I submit Opioid Substitution Treatment Prescription Forms via Healthmail?

Opioid Substitution Treatment (OST) Prescription Forms can be written and signed by the prescriber, scanned and then forwarded to the dispensing pharmacy via Healthmail. There is no requirement for a paper copy to be posted to the pharmacy also. Opioid Substitution Prescription Forms are the HSE required prescribed format. No other format to generate a valid OST prescription is allowed and other than the original being presented, only Healthmail can be used for the transfer of Opioid Substitution Treatment Prescription Forms.

12. If I have a query in relation to claims and payments who do I contact?

Queries may be submitted via the below methods. However, the preferred option is via email at this time.

In writing: Doctors Unit
HSE – Primary Care Eligibility & Reimbursement Service
P.O. Box 2828
Finglas
Dublin 11
D11 PX10

By Phone: 01 864 7100 option 2

By Fax: 01 89414895

By Email: PCRS.DoctorsQueries@hse.ie

Queries in relation to the recent amendments to legislation can be directed to pharmacy.response@hse.ie.