



Circular 016/20

17th April 2020

Dear Pharmacist,

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 Pharmacists in this regard.

Your co-operation and ongoing support is appreciated.

Yours faithfully,

Shaun Flanagan
Primary Care Reimbursement and Eligibility



Community Pharmacy Contractors Frequently Asked Questions – Part 2 COVID-19 (Coronavirus)

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 pharmacists.

A further set of FAQs have been developed to assist pharmacy contractors in this regard. Please ensure that these are read in conjunction with Pharmacy Circular 10/20.

The HSE website (www.hse.ie/coronavirus) is updated on a regular basis for the most up to date COVID-19 information. Pharmacists should also keep up to date with information provided by the Pharmaceutical Society of Ireland (www.thepsi.ie) and the Health Protection Surveillance Centre (www.hpsc.ie).

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 subject to the requirements for repeat dispensing of S1A and S1B medicinal products.

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. Prescriptions transferred via Healthmail must be kept for 2 years. The pharmacy must print a copy of the prescription as transmitted and treat it as an original prescription for the purposes of record-keeping, reimbursement and also to assist with dispensing preparation and checking.

Healthmail, secure clinical email, is a service that allows health care providers to send and receive clinical patient information in a secure and timely manner. It is a valuable means of communication between pharmacists and prescribers 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.

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

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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:

- 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.

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

5. How do I manage my GMS claims for submission at the end of the month where I have received prescriptions via Healthmail?

The valid prescription, for a patient with GMS eligibility when received via Healthmail must be printed as transmitted and then treated as an original prescription for the purposes of record keeping and reimbursement. 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. The prescription must include a valid GMS number. The prescription is endorsed and the form number entered in the top corner in the usual manner. The print out of the prescription is inserted into the paper bundle for submission with the end of month claims to PCERS. Pharmacy contractors should continue to retain the usual supporting documentation at the end of the month until further notice.

However, manual claimers have to submit their paper bundles in the normal manner for their claims to be processed. If you are a manual pharmacy, and the usual GMS Paperwork is not available, you will need to attach a unified claim form that includes the relevant drug code and quantity to the print out of the prescription via Healthmail and submit to PCERS for processing.

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.

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.

6. My GMS patients are having difficulty obtaining their prescription from the GP and do not have any further GMS prescriptions for their ongoing repeat medications. I have an original GMS prescription which has been dispensed already in March 2020. Can I use this as an ongoing prescription?

Yes – an original GMS prescription will be valid for ongoing supplies during the COVID-19 period. As above, amendments to the legislation has extended the validity of prescriptions from six to nine months and enables pharmacists to make additional supplies of prescription only medicines to patients from an existing prescription subject to the requirements for repeat dispensing of S1A and S1B medicinal products (refer to question 7). Repeats can include Schedule 4 Part 1 Controlled Drugs, if specified by the prescriber.

The validity of Schedule 2 or 3 Controlled Drug prescriptions remain at 14 days.

Repeated prescriptions must be endorsed in the normal manner and a photocopy of the original prescription inserted into the claims bundle for that month. Where updated prescriptions can be obtained, they should in order to ensure appropriate continued treatment.

7. The GMS prescription contains an S1A product, can I dispense a further supply?

A GMS prescription that contain S1A medicinal products that would not ordinarily be endorsed to be repeated can be dispensed on no more than four occasions within the new 9 month period of validity, 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. This excludes Schedule 2, 3 or 4 Part 1 Controlled Drugs.

It is important to note that the restrictions in relation to Isotretinoin remain as per Regulation 7(9) – *“The prescription in the case of a medicinal product, not being a medicinal product for external use, which consists of or contains Isotretinoin, and which is intended for the treatment of a woman of childbearing potential, shall not be dispensed later than seven days after the date on the prescription and the treatment on foot of the said prescription shall not exceed a period of thirty days.”*

Please note that where the number of occasions specified on the prescription for an S1B medicinal product has been reached, the product may be dispensed on three further occasions within the new 9 month validity period of the prescription, where in the opinion of the pharmacist it is appropriate and necessary for the continued treatment of the person for further supplies to be made.

Where a GMS prescription is repeated, it must be endorsed in the normal manner and a photocopy of the prescription inserted into the claims bundle for that month. The original prescription can then be kept by the pharmacist for the following months' supply as outlined above.

8. In the absence of an original prescription for a patient with eligibility under Community Drug Schemes, can I provide an emergency supply?

Under the COVID-19 Emergency Provisions, a pharmacist can now dispense **up to 10 days' emergency supply** of a prescription only medicinal product at the request of a patient. However, the pharmacist must be satisfied that:

- there is an immediate need for the medicine to be supplied and it is impracticable to obtain a prescription without undue delay,
- the treatment has been prescribed for the patient on a previous occasion, and
- they can safely specify the dose of the medicine for the patient.

Prior to the amendments, an emergency supply of a Controlled Drug in Schedule 2, 3 or 4 was not permitted, with the exemption of phenobarbitone supplied for the treatment of epilepsy. The amendments to the legislation permit a pharmacist to supply a Schedule 2, 3 or 4 Controlled Drug at the request of a patient or 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.

In the circumstances arising from the COVID-19 emergency, a pharmacist can supply **up to 10 days' emergency supply** of midazolam, clobazam and clonazepam for the treatment of epilepsy (Schedule 4 Part 1 Controlled Drugs) at the request of a patient. A prescriber can also request an emergency supply of midazolam, clobazam and clonazepam for the treatment of epilepsy.

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).

9. Does the amended period of validity extend to High Tech Prescription Forms?

Yes – High Tech Prescription Forms are valid for 9 months where the prescriber has indicated 'repeat for six months' and it is the opinion of the pharmacist that it is appropriate and necessary for the

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continued treatment of the person for further supplies to be made. If the prescription was for a lesser period the amendments regarding S1A and S1B medicinal products apply. Please place the order using the most recent prescription.

10. What should I do if I have to temporary close my pharmacy?

Pharmacy contractors must make the HSE aware of temporary closures as they arise. Where a pharmacy has agreed transfer of High Tech patients from another pharmacy that has closed temporarily, the pharmacy should complete the change of nominated pharmacy process before placing orders to access deliveries seamlessly. If any issue arises with transfer of patients please contact the High Tech Hub at PCRS.HiTech@hse.ie or 01-8647135.

11. Can I dispense Methadone and Suboxone for my patients on the Central Treatment List from a prescription transferred via Healthmail?

Opioid Substitution Treatment 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. Pharmacy fees will only be paid for Methadone and Suboxone claims when dispensed from an Opioid Substitution Treatment Prescription Form (original or transferred via Healthmail).

12. How will I manage my end of month claims to PCERS?

As per Circular 10/20, pharmacy contractors should continue to retain the usual supporting documentation at the end of the month until further notice. Claims can be submitted electronically in the normal manner for reimbursement. However, manual schemes such as Dental, EU and Opioid Substitution Treatment claims are required to be submitted for reimbursement.

For exceptional items pharmacies may be required to scan and submit supporting documentation to PCRS.PPUInvoices@HSE.ie with GMS pharmacy number and contact details clearly identified.

If you are a manual pharmacy, and the usual GMS paperwork is not available, you will need to attach a unified claim form that includes the relevant drug code and quantity to the prescription received via Healthmail and submit to PCERS for processing. The PCERS Team will support you should you wish to move to electronic submission.

13. Are Private Hospitals used as public facilities during COVID-19 covered under the Hospital Emergency Scheme?

Yes – Any Hospital Emergency prescription or Hospice prescription will be encompassed by this facility until further notice. Supply of products can be extended to one month supply (where specified on the hospital prescription) under the Hospital Emergency Scheme on foot of the valid hospital prescription. This includes Schedule 2, 3 or 4 Controlled Drugs.

The transfer of a prescription between the hospital prescriber and dispensing pharmacy by electronic means is permitted using the National Electronic Prescription Transfer System only. A list of hospitals and health care agencies securely connected to Healthmail is available at www.healthmail.ie.

14. Will a mental health services prescription be accepted under the GMS scheme during the COVID-19 emergency?

Yes – a mental health services prescription 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.

15. How do I apply for approval under Discretionary Hardship Arrangements?

As outlined in Circular 10/20, applications must be submitted via secure email – i.e. Healthmail to novelhardship@hse.ie. PCERS are dealing with a large volume of requests at present, please ensure that only urgent queries are marked as such (e.g. palliative care / end of life medicines) to enable these to be prioritised. It is important that the pharmacy GMS contract number, pharmacy contact details, HD1 Form and a pro-forma invoice are enclosed to facilitate an efficient and seamless review of the approval request.

Claims under this arrangement are submitted in the normal manner (i.e. HD2 Form and supporting invoice) to the local health office.

16. My patients are requesting more than one month supply under Community Drug Schemes, can I provide more than one month's supply to them?

No – as per Circular 08/20, it is vital to continuity of supply of essential medicines that stockpiling at pharmacy or patient level does not occur and that one month's supply is the maximum quantity allowed under the GMS and Community Drug Schemes. Patients and the general public are asked not to seek supplies of medicines over and above their normal requirements. Doing so will disrupt existing stock levels and hamper the supply of medicines for others.

17. If I have a query in relation to reimbursement who do I contact?

Pharmacy contractors can continue to contact PCERS at 01-8647100. Pharmacy claim queries should be submitted using the Pharmacy Query Form which is available for download on the Pharmacy Application Suite and also at www.pcrs.ie > Online Services > Services for Pharmacists Only > Query Form for Pharmacists

Query Forms may be scanned and sent to our dedicated email address at pcrs.ppuqueries@hse.ie. Reclaims should not be sent in using this method of communication.

The High Tech Co-Ordination Unit can be contacted by email, PCRS.HiTech@hse.ie or by phone at 01-8647135.

Pharmacies can contact Pharmacy Function directly (option 7) in relation to reimbursement approvals (e.g. Termination of Pregnancy Stock Orders, PrEP, and Phased Dispensing) but it is preferable to email pharmacy.response@hse.ie.

Queries in relation to ONS approvals can be directed to PCRS.ONS@hse.ie.

Exempt Medicinal Product queries can be directed to PCRS.ExemptMed@hse.ie.

18. I have not submitted my training grant claim form to my local HSE Pharmacist, what should I do?

The training grant application form closing date of the 31st March 2020 has been extended to 30th September 2020. The annual application for approved courses should include the completed Pharmacy Training Grant Summary Form, and the individual Pharmacy Training Grant Claim Form(s) covering all relevant staff in the pharmacy. Each application, which should be forwarded to the relevant HSE Pharmacist at local level, should also include the pharmacy staff training plan for the current year.

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19. My normal opening hours on my Community Pharmacy Contractor Agreement have reduced, what should I do?

You should continue to notify your local HSE Pharmacist of any changes to opening hours so that our database of available pharmacy services is maintained accurately. A contact list of the HSE Pharmacists was issued with Circular 10/20. Many pharmacies have consolidated their contract opening hours, with the agreement on an individualised basis of the HSE, to support resilience in those contingency plans. In consolidating opening hours, pharmacies have developed separate teams so that continuity of service can be provided for a sustained period even if individual staff members become ill with COVID 19.

Any pharmacy closure needs to be reported to your local HSE Pharmacist and the PSI. The pharmacy contingency plan should ensure that there is a clear and accessible plan in place, individual to your pharmacy, in the eventuality of your pharmacy being forced to close temporarily.