

Guidance For Special Formulation And Unlicensed Products In Primary Care By Pharmacists Working Within NHS Grampian

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May 2026	Grampian Medicines Information Centre changed to Grampian Medicines Information Service	throughout the document
May 2026	RPS updated to Royal College of Pharmacy	throughout the document
May 2026	Pharmaceutical Specials Services Tayside Updated to NHS Scotland Pharmaceutical 'Specials' Service	throughout the document
May 2026	Clarification of definition of Special	Page 4 – 1.1. Definition of a Special
May 2026	Process for checking, authorising and ordering updated to provide clearer guidance	Page 6– 2. Process for Checking, Authorising and Ordering a Special for a Prescription
May 2026	Costing information to be supplied from at least two specials companies	Page 6 – 2. Process for Checking, Authorising and Ordering a Special for a Prescription
May 2026	Updated NHS Scotland Pharmaceutical 'Specials' Service and included other NHS manufacturing sites in England and wales	Page 6 – 2. Process for Checking, Authorising and Ordering a Special for a Prescription
May 2026	Requirement for re-authorisation if 20% variation of original cost	Page 6 –2. Process for Checking, Authorising and Ordering a Special for a Prescription
May 2026	Reauthorisation – removed form guidance as standard 12 month authorisation given	Reauthorisation (previously chapter 6)
May 2026	removed NHS Grampian special list of products can be requested from Specials Aberdeenshire email	Page 8 – 2.4. NHS Grampian Specials List

Revision Date	Summary of Changes	Changes Made
May 2026	Vitamins and Minerals revised for concise guidance	Page 9 – 2.5. Vitamins and Minerals
May 2026	Clarified cost is quantity to the patient	Page 9 – 2.7. Endorsing
May 2026	Clarified request form to be submitted as MS Word document	Page 10 – 3.Summary
May 2026	Guidance and further reading included link to Policy for the Use of Unlicensed Medicines	Page 11 - 4.References
May 2026	Consultation Group updated and moved as per new template	Page 2 - Consultation Group
May 2026	updated links and email contacts	Page 12 - Appendix 1 - Contact Information
May 2026	added prescriber clarification, request for two quotes from suppliers and request to annotate comments section with relevant information Re-authorisation after 12 months updated and removed.	Page 13 - Appendix 2 - NHS Grampian Specials Process - A Step by Step Guide
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Special Formulation And Unlicensed Products In Primary Care - A Guide For Pharmacists Working Within NHS Grampian

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Special Formulation and Imported Unlicensed Medicines in Primary Care - A Guide for Community Pharmacists Working within NHS Grampian

1. Introduction

This guidance covers the local NHS Grampian process for the ordering and supply of unlicensed special formulations and imported unlicensed medicines in Primary Care in line with PCA(P)(2015) 17 – “*Pharmaceutical Services: Amendments to Drug Tariff in respect of Special preparations and imported unlicensed medicines*”

[http://www.sehd.scot.nhs.uk/pca/PCA2015\(P\)17.pdf](http://www.sehd.scot.nhs.uk/pca/PCA2015(P)17.pdf) and the [NHSG Policy For The Use of Unlicensed Medicines \(Including Specials\)](#). This policy sets out mandatory governance requirements for the use of unlicensed medicines within NHS Grampian and should be referred to support decision making.

While it is recognised that sometimes it is necessary for an unlicensed medicine preparation to be prescribed in Primary Care the patient, prescriber and pharmacist should all be aware of all the implications around the supply.

This guidance aims to:

- Recognise Part 7S and Part 7U of the Scottish Drug Tariff.
- Support local implementation of Medicines and Healthcare Products Regulatory Authority (MHRA), Royal College of Pharmacy and General Medical Council (GMC) advice.
- Ensure that unlicensed special formulations or unlicensed imported medicines are not prescribed when appropriate licensed or more cost effective alternatives are available.
- Remind pharmacists of their responsibilities and liabilities with regard to the supply of unlicensed special formulations or unlicensed imported medicines
Outline the correct process to ensure that pharmacists:
 - o fulfil their legal and professional responsibilities
 - o know under what circumstances authorisation is a requirement for a unlicensed special formulations or unlicensed imported medicines
 - o know how to obtain authorisation for a unlicensed special formulations or unlicensed imported medicines
 - o know how to ensure full remuneration for the unlicensed special formulations or unlicensed imported medicines they supply.

1.1. Definition of a Special

The MHRA guidance describes the manufacture, import, distribution or supply of unlicensed medicines for human use (also known as ‘specials’) which do not hold a marketing authorisation in the UK granted by the MHRA.

If an unlicensed medicine is required to meet an individual patient’s special clinical need, then the MHRA provides guidance on the hierarchy for use of unlicensed medicines. ([The supply of unlicensed medicinal products special GN14.pdf](#))

If a bespoke unlicensed medicine is required to meet a patient's clinical need an unlicensed special formulation may be sourced.

For the purposes of this guide the term '**Special**' will be used and the products may include:

- Non-standard and therefore unlicensed strengths of existing licensed medicines.
- Non-standard presentations of existing active ingredients.
- Imported products not approved by MHRA (not otherwise available in the United Kingdom).
- Other products not otherwise commercially available.

Please note that the MHRA guidance on unlicensed medicines does not apply to a product made up directly by the pharmacist, on the direct order of a doctor or a dentist, for a specific patient. This means that the prescription form is within the building where the compounding is occurring (i.e. extemporaneous dispensing of a prescription by the pharmacist in their pharmacy) and not made by another provider on behalf of the pharmacy contractor.

1.2. Prescribed Specials – The Prescriber's Responsibilities

The prescriber should fully understand that prescribers of unlicensed medicines, or medicines prescribed outwith their marketing authorisation (off-label), have a personal liability for their prescription that cannot be transferred to the manufacturer or importer of the medicine.

1.3. Prescribed Specials – The Pharmacist's Responsibilities

The pharmacist directly supplying a Special bears shared clinical responsibility with the prescriber as to the suitability and safety of the product for use by the individual patient. The pharmacist is also considered the producer of the product (under the Medicines Act) and bears direct responsibility for the formulation, quality, presentation and labelling of the product and that it meets dispensing standards.

It should be noted that an unlicensed Specials UK manufacturer licence is specific to both the premises and the product. Some manufacturers may also make products that are not covered by their licence and it is up to the person ordering a product to ensure that the item ordered is covered by the Specials licence.

Supply of a Special should not be entered into without due consideration of the needs of the patient and suitability of the Special and must only be considered if there is no suitable licensed product available.

When presented with a new prescription for a Special, the pharmacist as purchaser of the item, has clear professional duties to discuss the appropriateness of the medication with the prescriber in terms of:

- Availability of any licensed product that is therapeutically equivalent.
- Informing/reminding the prescriber of their responsibilities in prescribing a Special including:

- o that they (the prescriber) will bear clinical responsibility for prescribing an unlicensed product
- o that full prescribing information about the product is not always available
- o the cost involved in obtaining the product.
- o the timescale for obtaining the product.

The pharmacist must inform/remind the patient that the product being dispensed is unlicensed and the implications of this, e.g. time delay.

Where an unlicensed medicine has been prepared under the manufacturing part of the Section 10 exemption from the Medicines Act 1968, by the pharmacist contractor or by a third party, the pharmacist must endorse the names, quantities and cost of the ingredients used in preparing the unlicensed medicine.

2. Process for Checking, Authorising and Ordering a Special for a Prescription

2.1.Process for community pharmacy

When a prescription for a Special is received in the pharmacy, the following steps and checks should be undertaken in every case.

- 1) Check if the patient has had the item dispensed before.
- 2) Check the BNF to see if a licensed alternative is available in a different form or as an alternative proprietary product in the same class.
- 3) Check if any licensed products could be used in an unlicensed way, e.g. tablets crushed or dispersed, or capsules opened. Ensure using the product in this way is it bioequivalent to the original. The Grampian Medicines Information Service at ARI may have information available to confirm this. In addition, the NHS SPS website has useful information available at [Swallowing difficulties – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice](#)
- 4) Check if the specifications can meet the requirements of the prescriber and the patient, including clinical suitability and formulation:
 - drug
 - route of administration
 - form
 - strength or concentration range
 - excipients
 - flavour, smell or appearance
 - number of tablets or volume of liquid for each dose
 - release characteristics and bioavailability
 - number of units required
 - any specific labelling or information needs
 - storage

Standardised formulations should be purchased wherever practicable.

- 5) Request costing information from at least two Specials Company or importer based on this specification (including postage and packing, delivery or handling charges).
Note: Information on the most cost effective supplier may already be available from the NHS Grampian Specials List. [Specials & Unlicensed Medicines – NHS Grampian](#)
Note: At this point it may also be useful to check with these suppliers if alternative forms or strengths of the preparation requested are available more readily (e.g. a higher strength liquid which would enable the prescribed dose to be easily given via an oral syringe). Also check the most cost effective quantity to purchase, e.g. 100 tablets may cost less than the 56 required.
- 6) Contact the prescriber to advise they have prescribed an unlicensed medicine and provide information on alternative products (where applicable), costs, timescales and to agree the prescription with the patient. Discuss the product options for the patient (strength, formulation form, presentation).
- 7) If the prescriber confirms that the Special is the most appropriate product for the patient, then NHS Grampian authorisation must be obtained prior to ordering the Special unless the product:
- is listed in Part 7S or Part 7U (see Section 7 below) of the Drug Tariff
 - can be prepared extemporaneously in the pharmacy
 - is available from NHS Scotland Pharmaceutical Specials, Tayside or any other NHS manufacturing unit in Scotland, England and Wales) at a more cost effective price than any alternate supplier.
 - is included in the NHS Grampian approved pre-authorised Specials List [Specials & Unlicensed Medicines – NHS Grampian](#)
 - A current authorisation for a named patient and medicine (max duration of authorisation is 12 months) has been obtained with less than 20% price variation from original authorisation
- 8) To request NHS Grampian authorisation, the contractor must fully complete the 'Request Form for Authorisation to Order Specials' (Appendix 3) and email to the Specials Team (gram.specialsaberdeenshire@nhs.scot) for approval by the appropriate Health and Social Care Partnership (H&SCP) lead pharmacist (see [Appendix 1](#)). The contractor must provide two quotes, detailing the lowest price for which the Special in question can be obtained and any handling/delivery charge. Any additional information to support the request should be documented in comments box. Authorisation will either be given at this point, or failing that, further investigation or alternative supply arrangements suggested.
Note: NHS Grampian reserve the right **not** to authorise the supply of a Special, if the product price quoted by the contractor is not considered to be the lowest purchase price available. Contractors may be required to seek alternative suppliers. Incomplete or incorrect request forms will be returned, which will delay the authorisation process
- 9) When authorisation is given, pharmacists will be provided with the authorisation number on an updated copy of the request form. This form should be saved and is valid for 12 months from date of authorisation.

- 10) Order the product from the agreed source.
- 11) When ordering a Special manufactured in the UK or another country, the pharmacist must also obtain a Certificate of Analysis (COA) or Certificate of Conformity (COC) from the supplier which should be retained by the community pharmacist with the authorisation form as part of the record of supply. For imported products licensed in the country of origin but do not hold a UK license, the manufacturer may not provide a COA/COC.
- 12) Appropriate records of the supply must be kept for 5 years.

2.2. Part 7U - Limited List of Reimbursable Unlicensed Products

- Part 7U is a list of marketed products without formal marketing authorisation that are not included in the ACBS list, but are supplied from time to time on prescription.
- The ISD price is obtained from a manufacturer's price list against a known branded product. Each line is expected to be held in stock by a large pharmaceutical wholesaler. Payment of "out of pocket expenses" is not allowed for these products as it is already factored into the drug tariff price.
- Part 7U is provided solely to facilitate correct reimbursement for these products. Inclusion of particular products on the list does not represent an endorsement by NHS Grampian that these products should be prescribed.
- NHS Grampian will follow up these lines under the "pay and report" process.

2.3. Product Specification for Specials Formulations

It is the responsibility of the pharmacist supplying a Special to understand and define the specification and formulation of the product that they require from the Specials manufacturer. As part of this, it is necessary for the pharmacist to fully understand the intended use of the medicine. The 'specification' will include information on formula, labelling and the storage requirements of the product and any other appropriate details, e.g. any patient information.

2.4. NHS Grampian Specials List

An NHS Grampian Specials List of products has been compiled and is available via Community pharmacy website ([Specials & Unlicensed Medicines – NHS Grampian](#)).

This list will be regularly reviewed and the latest update emailed to community pharmacy contractors from the Pharmaceutical Care Services Team.

This lists products, and their suppliers, where the price indicated is the benchmark price which will be used to provide authorisation for supply. Pharmacists are under no obligation to purchase the products from the manufacturers/suppliers specified. However, where a product appears on this list, NHS Grampian will guarantee only to authorise reimbursement to a contractor for that product at the price listed. Requests for these products must still be discussed with the prescriber to advise that it is an unlicensed medicine and to confirm there is no alternate licensed product available.

If a contractor can obtain a Special medicine at the same, or lower cost, than that specified in the NHS Grampian Specials List then authorisation is not required. Always check the latest list for details.

2.5. Vitamins and Minerals

If there is a licensed medicine available, then this should not routinely be substituted with food supplements. If an unlicensed medicine is specifically requested by a prescriber authorisation must be obtained.

2.6. Products Initiated In Hospital

If a patient has been discharged from hospital, or advised by a hospital specialist to be prescribed a Special, the hospital pharmacist can be contacted for advice on the specification, formulation and the source of supply. Where difficulty of supply is an issue, the Specials Team should be contacted for advice.

2.7. Endorsing

- Items listed in the drug tariff do not require to be endorsed with payment information, as these will be paid according to the prices listed in Part 7S or 7U. These prices are calculated to include handling charges and out of pocket expenses. No additional expenses will be paid unless in exceptional circumstances and these must be pre-authorised by the Health Board through the H&SCP Pharmacists ([Appendix 1](#)).
- The products included in the NHS Grampian approved Specials List must be treated in the same way as non-Part 7S/U items. Although they have been 'pre-authorised' they **must** still be endorsed as below.
- The endorsements required for non-7S/U items are:
 - o SP – Invoice price (excluding VAT) less any discount or rebate obtained
 - o XP hc3000 – £30 payment for sourcing the most cost-effective product
 - o XP pp – Any other Out of Pocket expenses
 - o MIL - manufacturer licence number
 - o BAN - batch number
- Endorsements **must** be made electronically using the pharmacy PMR system as well as on the paper prescription. Care must be taken to select the correct price. A copy of the invoice should be submitted to PSD along with the paper prescription.
- All costs must be in the format pppp, i.e. £30=3000.
- The cost is the quantity dispensed to the patient
- The invoice, or a legible copy, should be submitted to PSD with the paper prescription form as evidence of the claim, but the price claimed must be declared on the prescription form or PSD cannot make an accurate payment

2.8. Payment, Reimbursement or Recovery of Payment by Practitioner Services Division (PSD)

Information on payment for Specials is given in the Scottish Drug Tariff, Part 7S. Full instructions for required paperwork and endorsements for Specials prescriptions are available in PCA(P)(2015)17. <https://www.publications.scot.nhs.uk/> and [http://www.sehd.scot.nhs.uk/pca/PCA2015\(P\)17.pdf](http://www.sehd.scot.nhs.uk/pca/PCA2015(P)17.pdf) and in the Scottish Drug Tariff.

In line with MHRA Guidance, prescriptions for Special formulations that are deemed to be pharmaceutically equivalent to an existing licensed product would not be paid at invoice price unless it is proved that the licensed versions were genuinely unavailable or unsuitable for the patient. PSD maintains a list of products that are formally unobtainable, and this may be checked by contacting one of the pricing offices, Community Pharmacy Scotland or checking the Scottish Drug Tariff.

Pharmacists are reminded that under the Royal College of Pharmacy guidance they have an obligation to seek best value for the NHS. It is expected that in discharging their obligation pharmacies will obtain quotations for a particular product from different suppliers prior to requesting authorisation to order a Special.

Where the unlicensed medicine has been prepared under the manufacturing part of the Section 10 exemption from the Medicines Act 1968, the contractor will be paid the cost of the ingredients used to manufacture the product.

NHS Grampian will seek to recover any unauthorised expenditure; where authorisation has not been sought or where the contractor has purchased at a higher price than was pre-authorised. The difference between the expected price (where authorisation has not been sought) or the authorised price and the actual price paid will be reclaimed.

3. Summary

There are occasions, when after discussion with the prescriber, the patient's needs dictate that there is no other choice than to supply a Special product.

This NHS Grampian document describes the processes for obtaining a Special which will ensure reimbursement of the cost of that Special. Failure to follow the processes in this guidance and obtain authorisation when required may result in pharmacies not being fully reimbursed for the Specials medicines they have supplied.

The following directions apply:

- The Scottish Drug Tariff contains a list of Specials that attract a set reimbursement payment and which may be ordered without prior authorisation (Part 7S & Part 7U).
- Extemporaneous preparation, within the pharmacy, could be considered.
- Where NHS Scotland Pharmaceutical 'Specials' Service is used to obtain Specials (or other NHS Production Unit), these Specials may be ordered without prior authorisation unless a more cost effective supply can be obtained – refer to 5.7.

- Authorisation for Specials must be obtained prior to ordering except where
 - o the products are in Part 7S/7U of the Drug tariff
 - o prepared extemporaneously
 - o available from a NHS Production Unit e.g. Pharmaceutical Specials Services, Tayside
 - o Is on the NHS Grampian (pre) approved list.
 - o Authorisation must be requested by submitting the request form ([Appendix 3](#)) to the Specials Team ([Appendix 1](#)). The request form needs to be submitted as a word document. Alternate formats (PDF, photos) will be returned, which will delay the authorisation process.
- Pharmacy contractors must not proceed with ordering or supply of the item unless authorisation has been granted. Where authorisation is not granted further direction will be given by the Special team and the H&SCP lead pharmacists.
- Pharmacy contractors must keep full records of procurement and supply of Specials.

4. References

- 1) Healthcare Quality and Strategy Directorate Pharmacy and Medicines Division
[http://www.sehd.scot.nhs.uk/pca/PCA2015\(P\)17.pdf](http://www.sehd.scot.nhs.uk/pca/PCA2015(P)17.pdf)
- 2) Finance, eHealth and Pharmaceuticals Pharmacy & Medicines Division
[http://www.sehd.scot.nhs.uk/pca/PCA2013\(P\)04.pdf](http://www.sehd.scot.nhs.uk/pca/PCA2013(P)04.pdf)
- 3) MHRA at:
<http://www.mhra.gov.uk/Howweregulate/Medicines/Doesmyproductneedallicence/Medicineshatdonotneedallicence/index.html>
- 4) [NHSG Policy For The Use of Unlicensed Medicines \(Including Specials\)](#).
- 5) General Medical Council at (please copy and paste into web browser):
<https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices>

5. Responsibilities for implementation

Organisational:	Chief Executive and Management Teams
Corporate:	Senior Managers
Departmental:	Heads of Service/Clinical Leads
Area:	Line Managers
Hospital/Interface services:	Group Clinical Directors
Operational Management Unit:	Unit Operational Managers

Appendix 1 - Contact Information

Practitioner Services Division	(Ask for a Group Leader)	
	Aberdeen	Tel: 01224 358400
	Edinburgh	Tel: 0345 300 1024
	Glasgow	Tel: 0141 300 1300
Community Pharmacy Scotland	www.cps.scot	Tel: 0131 467 7766
ISD Customer Services Desk		Tel: 0131 275 7050
Scottish Drug Tariff web link	<u>Scottish Drug Tariff - Medical practice and pharmaceuticals - Resources and tools - Public Health Scotland</u>	
MRHA Website	<u>www.mhra.gov.uk</u>	
Pharmaceutical Specials Services, Tayside	tay.pssoffice@nhs.scot	Tel: 01382 496702
Grampian Medicines Information Service ARI	<u>gram.medinfo@nhs.scot</u>	Tel: 01224 552316
Pharmacy and Medicines Directorate	gram.pharmaceuticalcareservices@nhs.scot	
For authorisation of Specials requests		
H&SCP Specials Teams Aberdeenshire HSCP	<u>gram.specialsaberdeenshire@nhs.scot</u>	

Appendix 2 - NHS Grampian Specials Process - A Step by Step Guide

NHS Grampian Specials Process A Step by Step Guide

1. **Prescription received for new “Special” for an individual patient**
Is there an alternative licensed product that may be suitable (including off-label use)?
Is the “Special” clinically suitable for the patient?
2. Identify product specification
 - Can it be extemporaneously prepared in the pharmacy?
 - If not, identify - suitable supplier and obtain costs including postage and packing, handling charges, shelf life, etc.
3. Contact prescriber
 - Advise that the medicine is unlicensed and provide estimate of cost.
 - Advise on alternative licensed options or use of licensed medicines "off-label"
 - Does the prescriber still wish to continue to prescribe the Special?
 - The prescriber must be a Non-Medical Prescriber (NMP), GP or Consultant
4. If the prescriber does not wish to continue with a prescription for a Special - make alternative arrangements.
If they still wish to continue - follow the process below.
5. Is the product listed in Part 7S or 7U of the Drug Tariff?
Is the product on the NHS Grampian Specials List and can be obtained for the same price or less?
Is the preparation available from an NHS manufacturing unit within Scotland/ England/ Wales?

If Yes to above points – proceed with dispensing product.

If No - continue to follow the process below.
6. Request NHS Grampian authorisation
 - Complete a new Word form ‘Request Form for Authorisation to Order Specials’.
 - Provide the TWO lowest quotes from suppliers of the product.
 - E-mail fully completed form (attach as a word document) to the Specials Team email address.
 - Annotate the comments section with relevant information i.e. enteral tube in situ, recommendation from Specialist, new request or re-authorisation, variation of 20% in cost, etc
7. Form will be returned with an authorisation number or pharmacist will be contacted by Specials Team for further discussion.
The authorisation is valid for 12 months from date of approval.
8. Once authorisation has been obtained a supply can be made.
 - Endorse prescription electronically and on paper with invoice price ex VAT, less any rebate plus any additional costs **which have been authorised**.
 - Endorse the fixed non Part 7S fixed handling fee of £30.
 - If applicable, obtain a Certificate of Analysis (COA) or Certificate of Conformity (COC) from the supplier and retain within pharmacy as part of the record of supply.
 - Ensure that appropriate records of the supply are kept for 5 years.
9. Keep secure records of this supply and subsequent supplies of the authorised Special for the named patient.
10. Repeat reauthorisation must be requested:
 - If the price of the product varies by 20% or more from the agreed authorised price – complete a new Request Form.

Appendix 3 - NHS Grampian Request Form for Authorisation to Order Specials

This form must be completed if the product requested does not fall into any of the categories listed on page 5 of the NHS Grampian guidance "Special Formulation and Unlicensed Products in Primary Care – A Guide for Pharmacists" available at http://www.communitypharmacy.scot.nhs.uk/nhs_boards/NHS_Grampian/index.html

Pharmacy name: Contractor Code:	Medical Practice:
Pharmacy telephone number: Contact pharmacist name:	Name of Prescriber and Designation that the request has been discussed with:
Date request submitted:	Patient CHI number:
PRESCRIPTION DETAILS Name of product: Form & Strength Dose: Quantity:	SUPPLIER DETAILS Please state the most cost effective quote. Company name : Pack size: Cost per Pack: Quoted cost* for full quantity (excl VAT): Cost of Postage/Carriage: Any other additional cost: *Cost should be for the full quantity that will be dispensed
Have you discussed this request with the prescriber? YES ☐ Have you made the prescriber aware that the product is a Special? YES ☐ Is the prescriber aware of the implications of this? YES ☐ Have you suggested any licensed alternatives? YES ☐ NO ☐ Second supplier contacted for quote incl price YES ☐ Company name: Pack size: Cost per Pack: Quoted cost* for full quantity (excl VAT): Cost of Postage/Carriage & additional costs:	
Comments:	
Save the completed form and e-mail to for authorisation to:- gram.specialsaberdeenshire@nhs.scot The product must only be ordered after authorisation has been granted.	
Authorisation - to be completed by Authorising Officer: Product is authorised (for this patient) for 12 months from date below ☐ Authorisation number: Authorising Officer H&SCP: Date: Product has NOT been authorised ☐	
Specials Circular available at: http://www.sehd.scot.nhs.uk/pca/PCA2015(P)17.pdf • Records of ALL Special products supplied must be kept as detailed in the circular. • Prescription should be endorsed electronically and on paper as per the circular.	