



Department
of Health &
Social Care

From Maria Caulfield MP
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Caroline Nokes MP

Chair, Women and Equalities Committee

By email to: caroline.nokes.mp@parliament.uk

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Dear Caroline,

Hormone Replacement Therapy and Related Matters

Thank you for your letter of 12 May following my attendance at the Women and Equalities Committee on 16 March where I gave evidence to your inquiry into the menopause and the workplace.

Please be assured that the Government is fully committed to do more to support women going through the menopause, and I want to thank you for all your work on this important agenda.

Every patient who needs and has been prescribed hormone replacement therapy (HRT), should be able to access it quickly and without any worry. As I stated in the Committee, by April 2023 an HRT prepayment certificate (PPC) will be available for purchase for the cost of two standard prescription charges (currently a total of £18.70) and will be valid for 12 months. The holder of an HRT PPC will be able to get as many NHS prescriptions for medicines licensed for treatment of the menopause as they need for a set annual price, with no additional prescription charges for a full 12 months. There will be no limit on the number of times it can be used throughout the year.

While GPs do not issue PPCs, the patient will be able to buy the certificate through a simple online or telesales process or from a pharmacy registered to sell PPCs (as is the case for the existing PPC which is valid for all NHS prescription charges). When the patient collects their prescription from the pharmacy, they will show the certificate and no further prescription charge will be applied for medicines licensed for treatment of menopause.

I wish to clarify that the HRT PPC will relate only to the charges for an HRT prescription and will not change or replace the need for a patient to get a repeat prescription from their GP through the usual means. As the HRT PPC will be valid for a full year with no limit on its use for HRT, the length of the prescription will have no impact on the cost to the patient. Once a patient has purchased an HRT PPC, they

will pay nothing more in the 12-month period for these specific medicines, regardless of whether their treatment is prescribed monthly or 3-monthly, or for however many types of HRT hormones they are prescribed.

I share the Committee's desire to see access to HRT improved for all women. It is worth noting that 89% of NHS prescriptions are already free of charge for patients, due to the current exemptions that exist. Further, patients can buy general PPC's which can be used for any prescribed medicines, and which cap the cost at just over £2 per week. Patients on a low income can also apply to the NHS Low Income Scheme for exemption from prescription charges.

In addition, the National Institute of Health and Care Excellence's [NICE guidelines on menopause diagnosis and management](#) allow GPs to prescribe for periods of up to 12 months. The guidelines currently recommend that health and care professionals review each treatment for short-term menopausal symptoms at three months to assess efficacy and tolerability, and then annually thereafter (unless there are clinical indications for an earlier review). NICE guidelines do not make recommendations on prescription lengths, as that is a clinical decision, however NICE guidelines on frequency of clinical review allow women who are stable on HRT to receive longer prescription periods up to 12 months.

However, we recognise there are valid reasons for shorter prescription lengths, such as personalised care and the preferences of the patient, or to minimise wastage of medicines. We also need to consider the impact very carefully on the supply chain. If too many women moved to 12-month prescriptions now – i.e. where they collected 12 months of HRT in one go – then there is a very real risk of further disruption.

Turning to the issue of HRT supply, Maddy McTernan was appointed as Head of the HRT Supply Taskforce to engage across the sector, including with suppliers, their trade associations, wholesalers and pharmacists, on measures to provide flexibility and ensure the efficient use of current stock as well as increasing supply, both in the near term as well as providing stability for the future.

There are over 70 HRT products available in the UK and supply issues are affecting a very small number of those. The vast majority of HRT products remain in good supply and alternatives are available for any affected by supply issues. At the end of April, we issued three Serious Shortage Protocols (SSPs) to even out distribution of the most in-demand products. Since then, further stock of all three products has been delivered and one product, Premique Low Dose[®] modified-release tablets, has returned to good availability.

Further SSPs were issued on 20 May, following a roundtable hosted by the Secretary of State, bringing together suppliers and representatives from the wholesale and community pharmacy sector. These SSPs allow community pharmacists to supply specified alternatives, where appropriate. Allowing the pharmacist this flexibility without needing to seek authorisation from the prescriber, saves time for patients, pharmacists and prescribers and will help ensure more patients are able to access HRT.

NHS England and NHS Improvement (NHSE&I) have issued communications to primary care teams, including GPs and community pharmacists, to confirm that prescribers are not limited by formulary lists and are not prevented from prescribing a wide range of products. The communications point prescribers towards information on choosing alternative HRT products, provided by the [British Menopause Society resource on HRT supply](#) and information on which formulations are most appropriate for different populations and comorbidities, which can be found on the [NICE website](#). NHSE&I encourages prescribers to check the availability of HRT products **before** prescribing, by reviewing the [NHS England Specialist Pharmacy Service website](#) liaising with local pharmacies to identify available stocks and agreeing suitable alternatives where necessary.

Communications have also updated frontline staff on wider menopause work, including the HRT PPC and the Women's Health Strategy. I have annexed the text of a bulletin sent to 30,000 teams across general practice, dentistry, community pharmacy and optometry in England, at Annex A.

The Medicines and Healthcare products Regulatory Agency (MHRA) has reminded both HRT manufacturers and suppliers of the action they can take to ease supply shortages and has supplemented existing guidance on these by holding workshops with representatives of manufacturers, community pharmacies and wholesalers to ensure these provisions are understood. This includes confirming that pharmacies have the flexibility to share medicines, where appropriate. MHRA is also working to consolidate their guidance so that it is available from a single webpage and this will be available shortly.

Your letter also asked when the Women's Health Ambassador will be appointed. In December 2021 we announced plans to appoint the first ever Women's Health Ambassador for England. The Ambassador will focus on raising the profile for women's health, increasing awareness of taboo topics, and bringing in a range of collaborative voices to implement the Women's Health Strategy. Applications for the Women's Health Ambassador post were launched as an expression of interest on 14 January and closed on 28 January. The role, description and application instructions were on the DHSC 'working for us' page on gov.uk, and anyone could apply by emailing their application to womenshealthrecruitment@dhsc.gov.uk. The Ministerial appointment process is ongoing, and I hope that the Government will announce the new Women's Health Ambassador in the near future.

Finally, we know there is still much more to do to ensure we improve menopause care more broadly, and I look forward to continuing the conversation on this critical matter.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'Maria'.

MARIA CAULFIELD MP

Management of hormone replacement therapy (HRT) supply

DHSC has issued serious shortage protocols (SSPs) for three products: Oestrogel pump-pack 750mcg/actuation gel, Ovestin 1mg cream and Premique low dose 0.3mg/1.5mg modified release tablets. “Pharmacists therefore only dispense three months’ supply, irrespective of whether the prescription is for longer provided the patient gives their consent”. To support the management of HRT supply, prescribers are encouraged to limit prescriptions for **all** HRT products to 3 months’ supply.

Prescribers in primary care are guided by local formularies but this does not prevent prescribing of a wider range of products (listed in the BNF) if, for example, the formulary products are in short supply. The [British Menopause Society resource on HRT supply](#) provides information on choosing alternative HRT products. Furthermore, information on which formulations are most appropriate for different populations and comorbidities can be found on the [NICE website](#).

We encourage prescribers to check the availability of HRT products **before** prescribing, by reviewing the [NHS England Specialist Pharmacy Service website](#), liaising with local pharmacies to identify available stocks and agreeing clinically suitable alternatives where necessary.

Wider work on menopause

DHSC plans to introduce an HRT-specific pre-payment certificate (PPC) by April 2023, meaning women can pay a one-off charge (currently £18.70), which is equivalent to two single prescription charges, for all their HRT prescriptions for a year. The PPC will mean women can access HRT on a month-by-month basis, easing pressure on supply while keeping the costs low.

This forms part of the wider DHSC priority to increase support for menopausal and peri-menopausal women. As set out in the [Vision for the Women’s Health Strategy](#), the menopause will be a key priority in the first government-led Women’s Health Strategy for England. In addition, the RCGP, RCOG and BMS have recently issued a [joint position statement](#) on menopause, which brings together advice and resources for healthcare professionals.