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BY EMAIL ONLY

Deputy Jim O'Callaghan
Dáil Éireann
Leinster House
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13th February 2023

PQ2768/22- Deputy Jim O'Callaghan- To ask the Minister for Health if general practitioners are permitted to prescribe Paxlovid for vulnerable people with Covid outside of a hospital setting and if not, if this can be permitted; and if he will make a statement on the matter.

Dear Deputy O'Callaghan,

Thank you for your representation.

Paxlovid™ was granted conditional marketing authorisation by the European Medicines Agency (EMA) in January 2022 and became available for use in Ireland in April 2022.

The HSE-COVID-19 Therapeutic Advisory Group (TAG) recommended considering Paxlovid™ for patients in Tier 1 and 2 risk groups (Appendix 2 of the HSE Interim Guidance for the Pharmacological Management of Patients with COVID-19) with conditions listed in the Clinical Risk Factor table (Appendix 3 of the HSE Interim Guidance for the Pharmacological Management of Patients with COVID-19), as these cohorts are at the highest risk of severe disease and they are expected to receive the greatest benefit:

<https://www.hse.ie/eng/about/who/acute-hospitals-division/drugs-management-programme/hse-interim-guidance-for-the-pharmacological-management-of-patients-hospitalised-with-covid-19.pdf>.

In July 2022, the HSE COVID-19 TAG and HSE clinical prioritisation subgroup, due to the high levels of community transmission of COVID-19 at that time, recommended the inclusion of an additional patient tier, tier 3 (Appendix 2 of the HSE Interim Guidance for the Pharmacological Management of Patients with COVID-19), where Paxlovid™ use is now recommended.

This update was communicated to prescribers on 08/07/2022:

<https://www.hse.ie/eng/staff/pcrs/circulars/gp/gp-circular-020-22-update-from-mmp-paxlovid.pdf>

Prescribing of Paxlovid™ may take place in the acute hospital or community setting and a number of communications have been issued to general practitioners (GPs) in relation to the use of Paxlovid™ (outlined below).



Prescribing of Paxlovid™ is also supported by a bespoke drug-drug interaction enquiry service for GPs by the National Medicines Information Centre (NMIC) and additional supports for GPs to undertake patient assessment for their suitability for Paxlovid™ are available.

The following communications have been issued to GPs (and other prescribers) in relation to Paxlovid™:

- [MMP letter dated 12/04/2022 from Prof. Michael Barry \(National Clinical Lead, MMP\)](#) providing an update to GPs on the availability of Paxlovid™ in Ireland.
- [Letter dated 14/04/2022 from Dr. Colm Henry \(Chief Clinical Officer \[CCO\], HSE\)](#) providing an update on new therapeutic agents for COVID-19-Paxlovid™ (PF-07321332+ritonavir) sent to GPs. This information was also communicated to Hospital Group CEOs on 08/04/2022 by the CCO.
- [MMP letter dated 08/07/2022 from Prof. Michael Barry](#), providing an update to GPs on additional recommendations from the HSE COVID-19 TAG and HSE clinical prioritisation subgroup.

This communication was also distributed to Hospital Group CEO's from Acute Operations on 12/07/2022 and was sent to Chief Pharmacists in public and private hospitals via the Acute Hospitals Drug Management Programme (AHDMP) on 14/07/2022.

- The NMIC published a [Therapeutics Today bulletin in July 2022](#) providing an update to doctors and pharmacists in relation to Paxlovid™ including resources available to support its prescribing.
- The HSE has published [Interim Guidance for the Pharmacological Management of Patients with COVID-19](#), including information on Paxlovid™, developed by the COVID-19 Therapeutics Guideline Expert Committee.
- The HSE National Director for Community Operations sent a Memo dated 10/11/2022 to Chief Officers in relation to Paxlovid™ prescribing guidance for community residential care facilities. The HSE National Director for Community Operations included an instruction that the information in the memo, which included the document [Paxlovid™ Prescribing Guidance Summary for Community Settings](#) is provided to prescribers/persons in charge in all community residential care facilities and private nursing homes.
- On 14/11/2022, the NMIC published the [November 2022 Therapeutics Today bulletin](#) providing an update to doctors and pharmacists in relation to Paxlovid™ to support its prescribing, including information on eligibility and prescribing considerations, drug-drug interactions and supply.
- [MMP letter dated 20/12/2022 from Prof. Michael Barry \(National Clinical Lead, MMP\)](#) providing a reminder to GPs on the availability of Paxlovid™ in Ireland and of the resources available to support its prescribing.
- In January 2023, the Antimicrobial Resistance and Infection Control Division (AMRIC) in collaboration with the Irish College of General Practitioners and relevant stakeholders in the HSE, updated the Paxlovid™ summary for GPs entitled [Paxlovid™ Prescribing Guidance Summary for Community Settings](#).



I hope this provides you with some assistance.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Sharon Hayden', written in a cursive style.

Sharon Hayden
General Manager
Office of the CCO