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Deputy Louise O'Reilly
Dáil Éireann
Leinster House
Kildare Street
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22nd July 2022

PQ 37299/22- Deputy Louise O'Reilly-To ask the Minister for Health the reason that there are differences in the official guidelines for the use and provision of anti-viral treatments compared to the regulatory approval and licence; and if he will make a statement on the matter.

Dear Deputy O'Reilly,

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 potential for global logistical or supply constraints for COVID-19 medicines makes patient triage and prioritisation necessary in this setting.

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 current high levels of community transmission of COVID-19, 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.

I hope this provides you with assistance.

Yours sincerely

Sharon Hayden
General Manager
Office of the CCO