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BY EMAIL ONLY

Deputy Jim O'Callaghan Dáil Éireann Leinster House Kildare Street Dublin 2

13/12/2021

PQ 58898/21- Deputy Jim O'Callaghan- To ask the Minister for Health if monoclonal antibody medicine, onapreve is available in Ireland for Covid-19 patients (details supplied)

Dear Deputy O'Callaghan,

The evidence base for therapeutics for COVID-19 is increasing rapidly, and some treatments of proven benefit have emerged. Numerous randomized trials of many drugs are underway to inform clinical practice. Treatments authorised in the European Union to treat COVID-19 following evaluation by the European Medicines Agency (EMA) include Ronapreve.

For any drug authorised for use by the EMA, the HSE is required to apply the statutory instruments as per the Health (Pricing and Supply of Medical Goods) Act 2013 in the procurement of medicines.

The Chief Clinical Officer of the HSE has commissioned a group to provide clinical advice and recommendations to support the future procurement and roll out of approved COVID 19 therapeutic drugs, given the development of these specific medicines.

This group will support implementation by developing clear guidance and providing clinical leadership to support care pathways and equitable access based on clinical need and prioritisation where therapeutic drug supply is limited.

The route of market access to such medications is not yet known and being managed at Department of Health level.

I hope this provides you with assistance.

Yours sincerely,

Sharon Hayden General Manager Office of the CCO