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PQ 49530/25 To ask the Minister for Health if the HSE would consider funding CAR T-cell therapy for cancer patients in Ireland; and if she will make a statement on the matter

Dear Deputy O Shea,

Chimeric antigen receptor T cell (CAR T-cell) therapy is a type of immunotherapy that is a very complex and specialist treatment and one which is customised for each individual patient.

CAR-T cell therapy is available for adults in Ireland in the hospitals designated to provide this service. The service has been available in St James's Hospital (SJH) since December 2021 and University Hospital Galway (UHG) are currently in the process of establishing a similar service.

Six CAR-T therapies are licensed as medicines by the EU; some with overlapping indications. Of these six, currently four indications have been approved for reimbursement by the HSE. There are other indications under consideration by the HSE and people with other types of cancer might have it as part of a clinical trial.

The HSE has a standard assessment process in place for the consideration of the reimbursement of new drugs and new indications for existing drugs. This process is intended to arrive at decisions on the funding of drugs that are clinically appropriate, fair, consistent and sustainable. The assessment process is underpinned by the Framework Agreement on the Supply and Pricing of Generic, Biosimilar and Hybrid Medicines (2021) and the Health (Pricing and Supply of Medical Goods) Act 2013. All cancer drugs including immunotherapy agents which have been approved for reimbursement since 2012 have gone through this process. Before a medicine is licensed for use and can be marketed for sale in the European Union, it must receive a market authorisation (license) from the European Medicines Agency (EMA), which as per the above may include an age restriction. Once a drug/ drug indication is licensed the company may apply to the HSE for reimbursement approval using the standard assessment process. The authority to approve the expenditure of funds on new medicines or new uses of existing medicines across the HSE is reserved to the HSE National Senior Leadership Team.

Yours sincerely,

Patricia Heckmann
Assistant National Director
National Cancer Control Programme