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Albert Dolan, T.D.
Dáil Éireann,
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Dublin 2.

4th November 2025

PQ: 56636/25

To ask the Minister for Health the communication and support provided to patients being switched to best value medicines; the monitoring which has been undertaken on patient outcomes and acceptance of switching; and if she will publish the data annually; and if she will make a statement on the matter. -Albert Dolan

Dear Deputy Dolan,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 56636/25), which you submitted to the Minister for Health for response.

The HSE Medicines Management Programme (MMP) has developed a suite of resources to support clinical teams in prescribing the recommended best-value biological (BVB) medicines/best-value medicines (BVMs). These include:

- Product information sheets for each of the recommended BVB/BVMs
- Template switching letters for BVB/BVMs for clinical teams to amend for use within their own clinics
- Patient information sheets for each of the BVB/BVM processes.

The above resources are suitable for use with patients who are commencing treatment with a particular medicine or if they are being switched to one of the recommended BVB/BVMs. They are available on the MMP website.

In addition, the MMP has engaged with relevant patient support groups in relation to the BVB/BVMs. This has included engagement with Arthritis Ireland, the Irish Society for Colitis and Crohn's Disease (ISCC) and MS Ireland. The MMP has assisted these groups to develop information for patients on biosimilars and BVB/BVMs. The patient information leaflet that was developed for patients by the ISCC in collaboration

with the MMP and the National Clinical Programme for Gastroenterology & Hepatology is an example of this:
https://www.hse.ie/eng/about/who/cspd/medicines-management/best-value-medicines/best-value-biological-medicines/iscc-biosimilars-patient-information-leaflet.pdf

The MMP, in conjunction with the HSE Primary Care Reimbursement Service (PCRS) High Tech Co-ordination Unit, delivers information sessions to clinical teams on biosimilar medicines, the BVB/BVMs and the High Tech Hub. These sessions include information on the resources that are available to clinical teams to support them in initiating and switching patients to the recommended BVB/BVMs.

Information is recorded by clinical teams at an individual patient level in the medical notes that are available for each patient in hospitals. Aggregated data is not captured at a national level on patient outcomes or acceptance of switching with respect to individuals who have been switched to a BVB/BVM. A high level of uptake of the BVB/BVMs is noted, with an overall uptake rate of 93.5% of patients in receipt of a BVB/BVM in September 2025 on the High Tech Arrangement for the seven medicines on the HSE Reimbursement List (adalimumab, etanercept, filgrastim, glatiramer, lipegfilgrastim, pegfilgrastim and teriparatide) for which the MMP has recommended BVB/BVMs.

In line with the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2024 (S.I. No. 73/2024), prescribers may issue prescriptions with a legally validity of up to 12 months where they deem it clinically appropriate. In order to access a BVB/BVM, a patient is required to have a legally valid prescription. This facilitates ongoing monitoring of patients, as they require a new prescription from the clinical team responsible for their care at least once every year in order to continue to receive the BVB/BVM.

The Health Products Regulatory Authority (HPRA) is responsible for monitoring the safety of medicines available for use in Ireland through pharmacovigilance. They operate a system through which reports of suspected side-effects can be made by both patients and healthcare professionals. These reports are reviewed and assist in gathering information about medicine use. Following initial authorisation by the European Commission, biosimilar medicines are subject to additional monitoring. This means that, as they are newly available, they are monitored even more intensively than other medicines. The aim of this additional monitoring is to collect information as early as possible to further inform the safe and effective use of these medicines and their benefit-risk profile when used in everyday medical practice.

Information for patients on biosimilar medicines is available on the websites of the HPRA and the European Medicines Agency. This includes an information guide on biosimilar medicines for patients, published by the European Commission.

Yours sincerely,

Suzanne Doyle
Primary Care Reimbursement Service

The Health Service Executive operates the General Medical Services Scheme, which includes Medical Cards and GP Visit Cards, under the Health Act 1970, as amended. It has established a dedicated contact

service for members of the Oireachtas specifically for queries relating to the status of Medical Cards and GP Visit Cards applications, which the Deputy / Senator may wish to use for an earlier response. Tel: 01-8647180 / email: Oireachtas.pcrs@hse.ie