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Health Service Executive, Primary Care Reimbursement Service
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Duncan Smith, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

31st October 2024

PQ: 41482/24

To ask the Minister for Health if botox treatment for primary and secondary hyperhidrosis is fully funded by the State; the public hospitals where it is provided to public patients at no additional cost to them; if an entitlement for GMS patients for where said treatment is recommended by a medical consultant; and if he will make a statement on the matter. -Duncan Smith

Dear Deputy Smith,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 41482/24), which you submitted to the Minister for Health for response.

There is a National Application, Assessment & Decision Process for new medicines which is underpinned by Primary Legislation (Health (Pricing and Supply of Medical Goods) Act 2013) put in place by the Oireachtas. The HSE must comply with the relevant legislation when considering investment decisions around new medicines.

The Corporate Pharmaceutical Unit (CPU) is the unit within the HSE that is responsible for accepting and processing pricing and reimbursement applications from the pharmaceutical industry.

Pharmaceutical companies are required to submit formal applications to the HSE if they wish their medicines to be added to the list of reimbursable items covered under community drugs schemes and arrangements / funded via hospitals. In order to submit a formal application, the medicine must hold a marketing authorisation.

As per the summary of product characteristics (SmPC) for (Botox®), the method of administration details "Botox® should only be given by physicians with appropriate qualifications, and expertise in the treatment and the use of the required equipment".

https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA1824-017-002_13082024112348.pdf

https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA1824-017-001_22052024094139.pdf

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Where a licensed medicinal product is suitable (as per the product licence and criteria in line with the Health (Pricing and Supply of Medical Goods) Act 2013:) for self-administration or administration by a carer (i.e. not requiring administration or supervision of administration by a Health Care Professional) it may be considered eligible for inclusion under the Community Drug Schemes.

Hospital pricing approval is in place for Clostridium botulinum type A neurotoxin complex (Botox®) since 2010. The HSE CPU cannot comment on individual hospital arrangements/service provision.

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