Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

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Circular No. 006/10 5th March 2010

Re: Bendroflumethiazide (Actavis) Tabs. BP 2.5mg.
Bendroflumethiazide (Actavis) Tabs. BP 5mg.

Dear Pharmacist,

You will have previously been notified by Leo Pharma that Centyl Tablets 2.5mg. and Centyl Tablets 5mg. are being discontinued. The discontinuation relates to the Danish, Norwegian and Irish market. These were the only remaining EU countries in which these products had been marketed by Leo Pharma. There are now no authorised forms of this medicine available on the Irish market. Centyl K and Low Centyl K remain available on the market.

The HSE has engaged with a number of suppliers with the aim of ensuring continuity of supply of the discontinued medicines for Irish patients.

Actavis UK holds Marketing Authorisations in the UK for Bendroflumethiazide Tablets BP 2.5mg. and 5mg. and have agreed to apply for Marketing Authorisations to market the two products in Ireland.

Pending this application and during the application review process, Actavis have agreed to supply their two UK-authorised Bendroflumethiazide products to the Irish market under the Exempt Medicinal Products provisions.

The IMB has decided to waive (for these Actavis Bendroflumethiazide Tablets BP 2.5mg. and 5mg. products **only**) on a temporary basis one of the key documentation requirements that apply to wholesalers intending to supply exempt medicinal products to pharmacies and doctors. This is the requirement for the wholesaler to obtain written documentary evidence that the order is in response to the bona fide unsolicited order of a doctor for the treatment of a patient under his or her care. This requirement is based on Paragraphs 2 and 3 of Schedule 1 of the Medicinal Products (Control of Placing on the Market) Regulations, 2007.

This communication is intended to advise you that any order that your pharmacy places for Bendroflumethiazide-only tablets will require the supply of an unauthorised product for some time i.e. until an authorised product becomes available.

Wholesalers will be made aware that this communication has been sent to pharmacists and that a similar communication has also been sent to prescribers. On this basis, wholesalers will have sufficient evidence that any order they receive for a Bendroflumethiazide-only tablet product is in response to the bona fide unsolicited order of a doctor for the treatment of a patient under his or her care.

The justification for waiving this documentation requirement is to ensure continuity of supply of bendroflumethiazide tablet products pending formal application for Marketing Authorisations for these products and a decision in relation to that application. All other documentation requirements which apply to wholesalers intending to supply exempt medicinal products, such as the record keeping and batch tracking requirements, remain in place for these unauthorised Bendroflumethiazide products.
It is important to note that there is currently no Marketing Authorisation in place in Ireland for either of these medicines from Actavis.

It is important that you are aware that any order that you place for Bendroflumethiazide-only tablets will require supply of an unauthorised product for some time i.e. until an authorised product becomes available.

Because of the essential nature of these products and given the exceptional circumstances, as a temporary measure until such time as supplies of authorised products become available, Bendroflumethiazide tablets 2.5mg. (Actavis) and Bendroflumethiazide tablets 5mg. (Actavis) may be supplied and will be reimbursed under the GMS and Community Drug Schemes.

Therefore this product may be claimed by quoting the following relevant number –

Bendroflumethiazide (Actavis) Tabs. 2.5mg. 28 (A) - 55584

Bendroflumethiazide (Actavis) Tabs. 5mg. 28 (A) - 55585

The products are expected to be available through the standard wholesale distribution mechanisms.

The HSE has written to prescribers in relation to this issue.

I would appreciate your support and co-operation in this matter.

Yours faithfully,

Patrick Burke
Primary Care Reimbursement Service