



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Corporate Pharmaceutical Unit
Health Service Executive
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**Notice of a Proposal to make a relevant decision
under Section 24 of the Health (Pricing and Supply of Medical Goods) Act 2013**

Date: 22nd August 2013

The HSE hereby notifies relevant suppliers of its intention to set reference prices for the following interchangeable groups:

Atorvastatin 10mg Film-coated Tablets (IC0001-002-003)
Atorvastatin 20mg Film-coated Tablets (IC0001-003-003)
Atorvastatin 40mg Film-coated Tablets (IC0001-004-003)
Atorvastatin 80mg Film-coated Tablets (IC0001-005-003)

The HSE proposes that the following reference prices would be effective 1st November 2013:

Atorvastatin 10mg Film-coated Tablets (IC0001-002-003): €3.47 per 28 x 10mg tabs
Atorvastatin 20mg Film-coated Tablets (IC0001-003-003): €5.46 per 28 x 20mg tabs
Atorvastatin 40mg Film-coated Tablets (IC0001-004-003): €9.14 per 28 x 40mg tabs
Atorvastatin 80mg Film-coated Tablets (IC0001-005-003): €10.53 per 28 x 80mg tabs

The HSE hereby outlines the reasons on which this proposal is based:

(a) the ability of suppliers of the relevant listed items to meet patient demand for the relevant listed items,

The HSE considers that there is adequate evidence that suppliers are able to meet demand. On the basis of reimbursement claims made by pharmacy contractors there is substantial generic penetration. Generic suppliers have been able to meet a market demand growth from 0% penetration to almost 70% (March 2013) and growing since May 2012.

(b) the value for money afforded by the relevant listed items,

The HSE has received anecdotal and other information in relation to the atorvastatin market. It is clear that the current reimbursement price is significantly higher than the real market price of atorvastatin in Ireland. It is clear that the HSE and Irish patients are paying more for atorvastatin than other EU citizens and this is unsustainable.

(c) the equivalent relevant prices (if practicably available) of the relevant listed items in all other Member States where one or more than one of the relevant listed items is marketed,

The HSE commissioned the **Gesundheit Österreich Forschungs- und Planungsgesellschaft mbH** in Vienna, Austria to collate and provide detailed information in relation to pricing in the 28 European Union (EU) member states (MS). The Economic and Social Research Institute (ESRI) published comparison data in their report titled "Pharmaceutical Pricing, Prescribing Practices and Use of Generics" (July 2013). The HSE is aware of summary detail in relation to off patent medicine pricing that IMS recently collated during a review of pharmaceutical prices in Ireland in comparison to other Member States.

(d) the relevant prices of therapeutically similar listed items,

The HSE Medicines Management Programme has recommended that atorvastatin at current prices would not be the statin of choice for many patients. The price of atorvastatin is significantly above that of other statins. The

HSE considers that the reference price of other statins may also be set below existing prices if designated interchangeable.

(e) the resources available to the Executive, and

The Department of Health in introducing the Health Act made clear its view that the Act was introduced to drive reductions in the prices of medicines.

The Minister for Health in welcoming the passing of the Act said "This legislation gives effect to the commitment in the Programme for Government that reference pricing and greater use of generics would be introduced to reduce the State's large drug bill and the cost to individuals of their medicines. It will promote price competition and deliver lower medicine prices for both the State and patients".

The Director General Designate of the HSE stated in January 2013 when setting out the HSE Service Plan for 2013: "In 2013 the HSE continues to face the dual challenge of reducing costs while at the same time improving outcomes for patients. The approach adopted in this Service Plan places a priority on stabilising hospitals budgetary positions, maintaining community services levels at 2012 levels, and delivering further costs efficiencies in the primary care schemes and drug costs."

(f) the terms of any agreement in place (whether entered into before, on or after the commencement of this section) between the Executive and any representative body of the suppliers of drugs, medicines or medical or surgical appliances where the agreement relates, whether directly or indirectly, to the price of one or more of those items.

The HSE was required to consult with the APMI under the 2012 APMI Agreement. It complied with this requirement. It also offered other suppliers of atorvastatin containing products the opportunity to provide their perspective in advance of it publishing a proposal. The HSE circulated the commissioned EU comparator data to suppliers of atorvastatin containing products.

Overview of Reasons:

The HSE is mandated to deliver the maximum savings possible commensurate with maintaining supplies in the market place to meet patient needs.

The HSE considers that on the basis of the information provided and established in relation to EU member states prices that Ireland is a significant outlier in pricing of atorvastatin. Substantial price reductions are required to address this issue.

The HSE recognises that Ireland is a small market and has closely examined the pricing in other small markets. Even allowing for this consideration EU price comparison data supports substantial price reductions

Right to make relevant representations:

The HSE hereby notifies each relevant supplier of an interchangeable product which falls within any of the above groups of interchangeable medicinal products of their right to make relevant representations to the HSE within a period of 28 days after the supplier concerned has received this notice.

Any relevant representations should be made in writing to the following address:

HSE Corporate Pharmaceutical Unit, Dr. Steevens' Hospital, Dublin 8, Ireland.

Signed: 

Shaun Flanagan MPSI, Chief Pharmacist