



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Aonad Cógaisíochta Corparáideach
Feidhmeannacht na Seirbhíse Sláinte
Seirbhís Aisíoca Príomhchúraim
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Date: 22nd February 2016

**Notice of a decision under Section 24 of
the Health (Pricing and Supply of Medical Goods) Act 2013**

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

Donepezil 5mg Film-coated Tabs / Orodispersible Tabs (IC0062-001-015)

Donepezil 10mg Film-coated Tabs / Orodispersible Tabs (IC0062-002-015)

The following reference prices will be effective from 01/04/2016:

Interchangeable Group	Per 28
Donepezil 5mg (IC0062-001-015)	€9.24
Donepezil 10mg (IC0062-002-015)	€13.44

The HSE hereby outlines the reasons on which this decision 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 are sufficient suppliers to meet demand. Generic penetration of the reimbursed market had reached 95% by volume by October 2015.

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

There are no concerns arising which would merit delisting of Donepezil at this time. Market intelligence available to the HSE suggests that reimbursed prices are out of line with some suppliers market prices.

(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 has interrogated the Euripid database which is shared by European pricing and reimbursement agencies. The data available to the HSE in relation to donepezil suggests that current reference prices are significantly above the current EU averages / medians. The HSE has looked at the data from a number of perspectives including analysing the averages / medians across all EU member states, across the 9 country basket listed in the 2012 IPHA agreement, across the member states with similar GDPs. The HSE considers that significant room for price reductions remains in the Irish Donepezil market. Even at the proposed revised reference prices, Irish prices would be substantially higher than the prices in markets such as Sweden, Finland, Denmark, UK, Portugal and Belgium, most of whom have similar GDPs to Ireland.

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

Donepezil was only the second medicine used in the treatment of Alzheimer's disease considered for reference pricing. Memantine (the other agent) is in a different therapeutic group and is currently undergoing a reference price review.

(e) the resources available to the Executive, and

The outlook is extremely challenging for the Health Service Executive in 2016. The HSE must maximise the use of the resources available to it and failure to do so could have significant impacts on availability of services and therapies.

(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 received no representations in relation to this reference price within the notice period.

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 faces significant financial pressures in 2016. European pricing data available to the HSE supports price reductions. The HSE is seeking to be prudent and to balance value for money versus sustainability of supply in a small market.

Additional Information

The HSE is frequently asked to clarify the prices to wholesale & reimbursement prices which would match an individual reference price. The HSE provides these below for information. The HSE will implement any notified reimbursement prices changes on the 1st April 2016.

Price to wholesale	Reimbursement Price	Reference Price
€8.56	€9.24	€9.24
€12.44	€13.44	€13.44

Signed:



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