

Potential reference pricing of atorvastatin 10mg, 20mg, 40mg and 80mg
Paper for Association of Pharmaceutical Manufacturers of Ireland (APMI) Consultation
(APMI Agreement 2012)

The purpose of this paper is to set out the Health Service Executive (HSE) preliminary analysis (prior to consultation) as it considers the appropriate price to be set for the expected first group of products to be designated as interchangeable by the IMB i.e. presentations of products containing atorvastatin 10mg, 20mg, 40mg or 80mg tablets as single ingredients in any pack size

The Health (PRICING AND SUPPLY OF MEDICAL GOODS) ACT 2013 (Commencement) Order 2013 (SI 202 of 2013) was signed on the 19th June 2013. This paper reproduces relevant sections of the ACT and seeks to clarify HSE understanding / intentions as at 20th June 2013.

Section 24 of the **HEALTH (PRICING AND SUPPLY OF MEDICAL GOODS) ACT 2013 (SI 14 of 2013)** set outs the criteria and process which the HSE must consider when setting a reference price.

24.—(1) Subject to subsections (3) to (5) and section 25 and without prejudice to the generality of section 21(3), the Executive may set a price (in this Act referred to as the “reference price”) for a relevant group of interchangeable medicinal products in relation only to the listed items which fall within the group.

The HSE cannot make any decision in relation to a reference price in advance of an Irish Medicines Board (IMB) decision on interchangeability.

Under the 2012 APMI agreement the price of any generic product declared interchangeable by the IMB would immediately fall to a maximum price of 40% of the pre-patent price of the originator. The HSE will implement such reductions on the 1st day of the month following any decision of the IMB i.e. if the IMB makes a decision in August 2013, the price movements to 40% of pre-patent original price will be made on 1st September. This is entirely separate from the setting of a reference price. The HSE outlines in Table 1, Appendix 1 the 40% prices expected to apply from 1st September 2013 as per the 2012 APMI Agreement. The price of the originator Lipitor is due to reduce on the 1st November 2013 to 50% of its original price under the 2012 IPHA Agreement.

(2) Subject to section 25, the Executive shall review the reference price (if any) set for a relevant group of interchangeable medicinal products at least once a year but not more than once every 3 months and may, following any such review, set a new reference price for the relevant group of interchangeable medicinal products.

The HSE expects to set the price of any reference group in the first phase for a year to allow certainty for all stakeholders. However the HSE reserves the right to review any reference price set after 3 months if it considers that any reference price is not appropriate.

(3) The Executive shall, when setting a reference price for, or reviewing a reference price set for, a relevant group of interchangeable medicinal products take into account—

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

The HSE considers that in relation to the market for atorvastatin 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 (almost 70% by volume as shown in Figure 1). 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 considers that no issues arise in relation to value for money (VFM) that would merit delisting of atorvastatin at this time. The HSE however notes the advice of the Medicines Management Programme in relation to the optimal statin choice at current 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,

For the avoidance of doubt on price comparisons in Europe, 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 27 European Union (EU) member states (MS) and also Norway, Switzerland & Croatia. The HSE independently established the prices in Australia, Canada and New Zealand. Summary details of the findings are presented in figures 2 (10mg), figure 3 (20mg), figure 4 (40mg) and figure 5 (80mg). Additionally the HSE has reviewed the advice and findings of the Economic and Social Research Institute (ESRI) in their report titled "Pharmaceutical Pricing, Prescribing Practices and Use of Generics" (July 2013) and their previous 2012 report titled "Delivery of Pharmaceuticals in Ireland, Getting a Bigger Bang for the Buck". The HSE is also aware that other parties have referenced other data in discussions with the Troika. In particular, the HSE is aware that the IMS has recently completed 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 recently completed an analysis of the relative pricing of statins. The programme recommended that atorvastatin at current prices would not be the statin of choice for many patients. Atorvastatin is likely to be the first product to be reference priced and other statins are included in the list of the first 20 molecules proposed to be assessed by the Irish Medicines Board. 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 when a full examination of international pricing at individual product level begins (following IMB assessment).

The HSE for information purposes outlines in figure 6 a summary of current pricing of generic and branded statins.

(e) the resources available to the Executive, and

The Department of Health in introducing this legislation has made clear its view that at a policy level this legislation 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 DCEO / Director General Designate of the HSE, Mr. Tony O’Brien, commented 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.”

The HSE has received anecdotal and other information in relation to the scale of discounts on atorvastatin. It is clear that the official headline price bears no relation to the real market price of atorvastatin.

There has also been significant public discourse and commentary on the prices of medicines in Ireland. It is fair to say that there is evidence of public concern in that discourse.

The HSE considers that it is mandated to deliver the maximum savings possible commensurate with maintaining supplies in the market place to meet patient needs. The HSE recognises that the setting of reference prices is not an exact science. There is no empiric scientific data or system to which the HSE can refer to set a reference price.

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

However, given the significant size of the market for atorvastatin, it may not be typical of other medicines which will ultimately be referenced priced. Therefore, decisions of the HSE in relation to reference prices for atorvastatin may not be reproducible for other molecules.

(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 is required to consult with the APMI under the 2012 APMI Agreement. This paper summarises HSE analysis prior to that consultation process. The HSE considers, on the basis of the information available to it as of 20th June 2013 that reference prices which are at least 50% and up to 80% lower than the existing reimbursement prices of atorvastatin are merited.

The HSE will consider any information provided to it as part of the consultation with APMI which will take place. However while the HSE will agree to meet with APMI to better understand any views of its members, the HSE in the interest of transparency and accountability can only consider information provided in written format to it by the APMI.

(4) The Executive may use a competitive process to set the reference price for a relevant group of interchangeable medicinal products.

The HSE considers that a competitive process might have the potential to provide the greatest level of price reductions but remains cognisant of concerns raised about the sustainability of supply. There is also the possibility of short term predatory actions by some suppliers (to garner market share, eliminate competitors and then increase prices in future tender rounds) if prices were set by tenders which resulted in single suppliers.

In particular, the HSE has sought to understand the impact of tendering on the sustainability of supplies in other Member States where competitive pricing has been used. The HSE considers that there is sufficient cause for concern to indicate that tendering may not necessarily be optimal for security of pharmaceutical supply in a small regulated market like Ireland. Therefore, while the HSE reserves the right to engage in a tender process in the future, it does not propose to use a tendering process for this molecule at this time.

(5) Where a reference price has been set for a relevant group of interchangeable medicinal products, nothing in this section shall be construed to require the supplier of a relevant listed item to supply the relevant listed item at the reference price.

Noted by the HSE

(6) When the Executive sets a reference price for a relevant group of interchangeable medicinal products, it shall, not later than 4 weeks before the reference price takes effect, give notice in writing of the reference price to community pharmacy contractors.

Schedule 1, Part 4 and Section 25 of the **HEALTH (PRICING AND SUPPLY OF MEDICAL GOODS) ACT 2013 (SI 14 of 2013)** set out the criteria and processes which the HSE must follow when it intends to or has made a decision. The HSE has not yet made a decision but in the interests of transparency lays out its intended timelines.

If the IMB designates atorvastatin as interchangeable during August 2013, the HSE will shortly thereafter give notice in writing of a proposal to set reference prices for the various atorvastatin strengths. The notice will follow the format and process outlined in Schedule 1, Part 4 of the **HEALTH (PRICING AND SUPPLY OF MEDICAL GOODS) ACT 2013**. Suppliers will have the right to make representations in writing within 28 days.

If or when the HSE makes a final decision (after this 4 weeks notice period) it is required to give suppliers and community pharmacy contractors an additional 4 weeks notice as per Section 25. The HSE would expect to provide this second notice period commencing sometime in September and to implement reference prices for atorvastatin on the 1st of November 2013.

Note: these requirement do not prevent the HSE from reducing the price of generic products to 40% of the pre-patent price of the originator from 1st September 2013 as per the APMI commitment and the HSE hereby gives notice of its intention to do so. The HSE expects to set revised reimbursement prices as set out in Table Y from the 1st September 2013.

25.—(1) The Executive shall, as soon as is practicable after making a relevant decision (but, in any case, not later than 4 weeks before the relevant decision takes effect), give notice in writing of the relevant decision, together with its reasons for the relevant decision, to the suppliers of the relevant listed items which fall within the relevant group of interchangeable medicinal products the subject of the relevant decision.

If the IMB designates atorvastatin as interchangeable during August 2013, the HSE intends to have completed its deliberations on reference pricing to allow implementation by 1st November 2013. The HSE will publish a notice in writing of its proposed reference prices on its website. The HSE will also write to suppliers of generic medicines, originator and any parallel imported product which is reimbursable and their representative organisations. The HSE would expect to implement the reference price on the 1st of November 2013

Note: this requirement does not prevent the HSE from reducing the price of generic products to 40% of the pre-patent price of the originator from 1st September 2013 as per the APMI commitment and the HSE hereby gives notice of its intention to do so.

(2) The Executive may, in a relevant decision, specify a date, or the occurrence of an event, from which the relevant decision shall take effect.

The HSE will do so and in the interest of providing as much preliminary notice as possible to stakeholders confirms that it is working to have reference prices for all strengths of atorvastatin in place by 1st November 2013

(3) Part 4 of Schedule 1 shall have effect where the Executive proposes to make a relevant decision.

See above – the HSE expects to issue the required notice during August 2013

(4) In this section and Part 4 of Schedule 1 “relevant decision” means a decision of the Executive to set a reference price for a relevant group of interchangeable medicinal products.

Part 4 of schedule 1 of the **HEALTH (PRICING AND SUPPLY OF MEDICAL GOODS) ACT 2013 (SI 14 of 2013)** further specifies the processes the HSE must follow:

Decisions of Executive under section 24

1. Subject to paragraph 2, where the Executive proposes to make a relevant decision, it shall give notice in writing of the proposal to the suppliers of the interchangeable medicinal products which fall within the group of interchangeable medicinal products the subject of the proposal.

The HSE has outlined above its intended mechanism of communication. It is expected that this notice will be issued in August 2013.

2. A notice under paragraph 2 shall include—

*(a) a statement of the proposal of the Executive,
(b) a statement setting out the reasons on which the proposal of the Executive is based, and
(c) a statement that each supplier of the interchangeable medicinal products which fall within the group of interchangeable medicinal products the subject of the proposal has the right to make representations in writing (in this Part referred to as “relevant representations”) to the Executive with respect to the proposal within a period of 28 days after the supplier concerned received the notice or such longer period as the Executive permits in any particular case.*

The HSE will comply with all legal requirements

3. The Executive shall, after considering the relevant representations (if any)—

*(a) implement the proposal without modifications,
(b) subject to paragraph 4, propose modifications to the proposal, or
(c) decline to implement the proposal.*

The HSE will comply with all legal requirements

4. If the Executive, after considering the relevant representations, wishes to propose modifications to the proposal (including any proposal to which this paragraph has previously applied), then this Part shall have effect with respect to the proposal as modified by the Executive as it has effect with respect to the proposal before such modification.

The HSE will comply with all legal requirements

Summary of Expected Timelines

- IMB issued Atorvastatin Interchangeable Lists (4): 26th June 2013 (with notice period)
- HSE will undertake consultation with APMI: July 2013 (non statutory commitment)
- IMB expected to decide on Interchangeability: August 2013

If IMB designates atorvastatin as interchangeable in August 2013:

- HSE will reduce reimbursement price of generic atorvastatins as per APMI agreement: 1 September 2013 – independent of reference pricing process
- HSE expected to issue proposal to set reference prices (with notice period): August 2013
- HSE expected to make decision on reference prices: September 2013
- HSE issues 4 weeks notice to suppliers and community pharmacy contractors: Sept / Oct 2013
- HSE expected to implement reference prices for atorvastatin (Nov 2013)

Appendix I: Tables and Figures

Table 1: Proposed Reimbursement Prices from 1st September 2013 if IMB designates Atorvastatin as interchangeable

GMS Code	Drug Description	Manufacturers Name	Proposed Ex-factory Price	Proposed Reimbursement Price
41906	Atorvastatin (Pfizer) Film Coated Tabs. 10 mg. 30	PFIZER HEALTHCARE IRELAND	€9.17	€9.90
41930	Atorvas Film Coated Tabs. 10 mg. 28	ROWEX LIMITED,	€8.56	€9.24
41937	Atorvastatin (Actavis) Film Coated Tabs. 10 mg. 28	Actavis ireland ltd	€8.56	€9.24
41958	Atorvastatin (Dexel Pharma) Film Coated Tabs. 10 mg. 28	PINEWOOD HEALTHCARE GROUP	€8.56	€9.24
41965	Atorvastatin Mylan (Gerard Labs.) Film Coated Tabs. 10 mg. 28	GERARD LABORATORIES LTD	€8.56	€9.24
41973	Atorvastatin (Niche Generics) Film Coated Tabs. 10 mg. 28	NICHE GENERICS LIMITED	€8.56	€9.24
41990	Atorvastatin TEVA Film Coated Tabs. 10 mg. 28	Ivax (teva) pharmaceuticals ireland	€8.56	€9.24
42000	Torvacol Film Coated Tabs. 10 mg. 28	CLONMEL HEALTHCARE LTD.	€8.55	€9.24
42007	Torvan Film Coated Tabs. 10 mg. 28	PINEWOOD HEALTHCARE GROUP	€8.55	€9.24
42015	Atorvastatin (KRKA Pharma) Film Coated Tabs. 10 mg. 28	KRKA PHARMA DUBLIN LTD.	€8.56	€9.24
42020	Atorvastatin (Pinewood Healthcare) Film Coated Tabs. 10 mg. 28	PINEWOOD HEALTHCARE GROUP	€8.56	€9.24
15486	Atorvastatin (Actavis) Film Coated Tabs. 20 mg. 100	Actavis ireland ltd	€48.20	€52.06
41907	Atorvastatin (Pfizer) Film Coated Tabs. 20 mg. 30	PFIZER HEALTHCARE IRELAND	€14.46	€15.62
41931	Atorvas Film Coated Tabs. 20 mg. 28	ROWEX LIMITED,	€13.50	€14.58
41938	Atorvastatin (Actavis) Film Coated Tabs. 20 mg. 28	Actavis ireland ltd	€13.50	€14.58
41959	Atorvastatin (Dexel Pharma) Film Coated Tabs. 20 mg. 28	PINEWOOD HEALTHCARE GROUP	€13.50	€14.58
41966	Atorvastatin Mylan (Gerard Labs.) Film Coated Tabs. 20 mg. 28	GERARD LABORATORIES LTD	€13.50	€14.58
41974	Atorvastatin (Niche Generics) Film Coated Tabs. 20 mg. 28	NICHE GENERICS LIMITED	€13.50	€14.58
41991	Atorvastatin TEVA Film Coated Tabs. 20 mg. 28	Ivax (teva) pharmaceuticals ireland	€13.50	€14.58
42001	Torvacol Film Coated Tabs. 20 mg. 28	CLONMEL HEALTHCARE LTD.	€13.50	€14.58
42008	Torvan Film Coated Tabs. 20 mg. 28	PINEWOOD HEALTHCARE GROUP	€13.50	€14.58
42016	Atorvastatin (KRKA Pharma) Film Coated Tabs. 20 mg. 28	KRKA PHARMA DUBLIN LTD.	€13.50	€14.58
42021	Atorvastatin (Pinewood Healthcare) Film Coated Tabs. 20 mg. 28	PINEWOOD HEALTHCARE GROUP	€13.50	€14.58
41908	Atorvastatin (Pfizer) Film Coated Tabs. 40 mg. 30	PFIZER HEALTHCARE IRELAND	€24.19	€26.13
41932	Atorvas Film Coated Tabs. 40 mg.	ROWEX LIMITED,	€22.58	€24.38
41939	Atorvastatin (Actavis) Film Coated Tabs. 40 mg. 28	Actavis ireland ltd	€22.58	€24.38
41960	Atorvastatin (Dexel Pharma) Film Coated Tabs. 40 mg. 28	PINEWOOD HEALTHCARE GROUP	€22.58	€24.38
41967	Atorvastatin Mylan (Gerard Labs.) Film Coated Tabs. 40 mg. 28	GERARD LABORATORIES LTD	€22.58	€24.38
41975	Atorvastatin (Niche Generics) Film Coated Tabs. 40 mg. 28	NICHE GENERICS LIMITED	€22.58	€24.38
41992	Atorvastatin TEVA Film Coated Tabs. 40 mg. 28	Ivax (teva) pharmaceuticals ireland	€22.58	€24.38
42002	Torvacol Film Coated Tabs. 40 mg. 28	CLONMEL HEALTHCARE LTD.	€22.58	€24.38
42009	Torvan Film Coated Tabs. 40 mg. 28	PINEWOOD HEALTHCARE GROUP	€22.58	€24.38
42017	Atorvastatin (KRKA Pharma) Film Coated Tabs. 40 mg. 28	KRKA PHARMA DUBLIN LTD.	€22.58	€24.38
42022	Atorvastatin (Pinewood Healthcare) Film Coated Tabs. 40 mg. 28	PINEWOOD HEALTHCARE GROUP	€22.58	€24.38
25398	Atorvastatin (Actavis) Film Coated Tabs. 80 mg. 28	Actavis ireland ltd	€26.00	€28.08
41909	Atorvastatin (Pfizer) Film Coated Tabs. 80 mg. 30	PFIZER HEALTHCARE IRELAND	€27.84	€30.07
41933	Atorvas Film Coated Tabs. 80 mg. 28	ROWEX LIMITED,	€26.00	€28.08
41968	Atorvastatin Mylan (Gerard Labs.) Film Coated Tabs. 80 mg. 28	GERARD LABORATORIES LTD	€26.00	€28.08
41993	Atorvastatin TEVA Film Coated Tabs. 80 mg. 28	Ivax (teva) pharmaceuticals ireland	€26.00	€28.08
42003	Torvacol Film Coated Tabs. 80 mg. 28	CLONMEL HEALTHCARE LTD.	€26.00	€28.08
42010	Torvan Film Coated Tabs. 80 mg. 28	PINEWOOD HEALTHCARE GROUP	€26.00	€28.08
42018	Atorvastatin (KRKA Pharma) Film Coated Tabs. 80 mg. 28	KRKA PHARMA DUBLIN LTD.	€26.00	€28.08
42023	Atorvastatin (Pinewood Healthcare) Film Coated Tabs. 80 mg. 28	PINEWOOD HEALTHCARE GROUP	€26.00	€28.08

Figure 1: Generic Market Penetration (by volume) (Source: Primary Care Reimbursement Service (PCRS) Database)

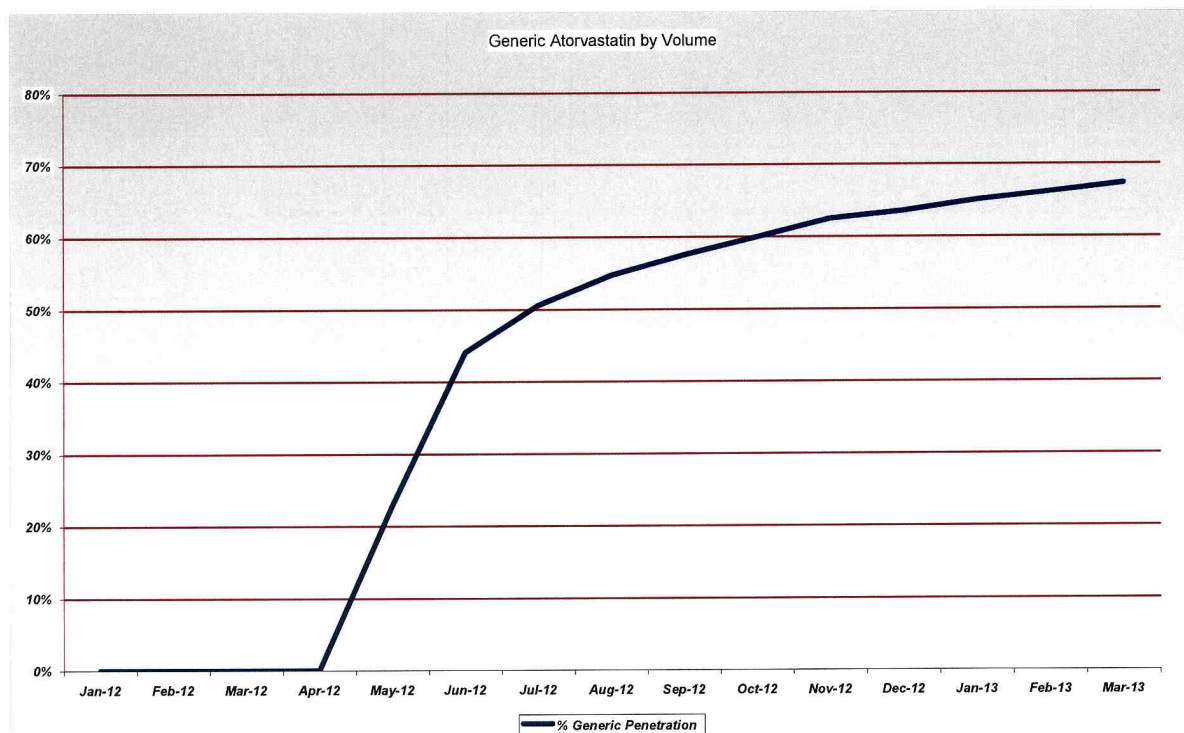


Figure 2: 10mg Atorvastatin International Pricing

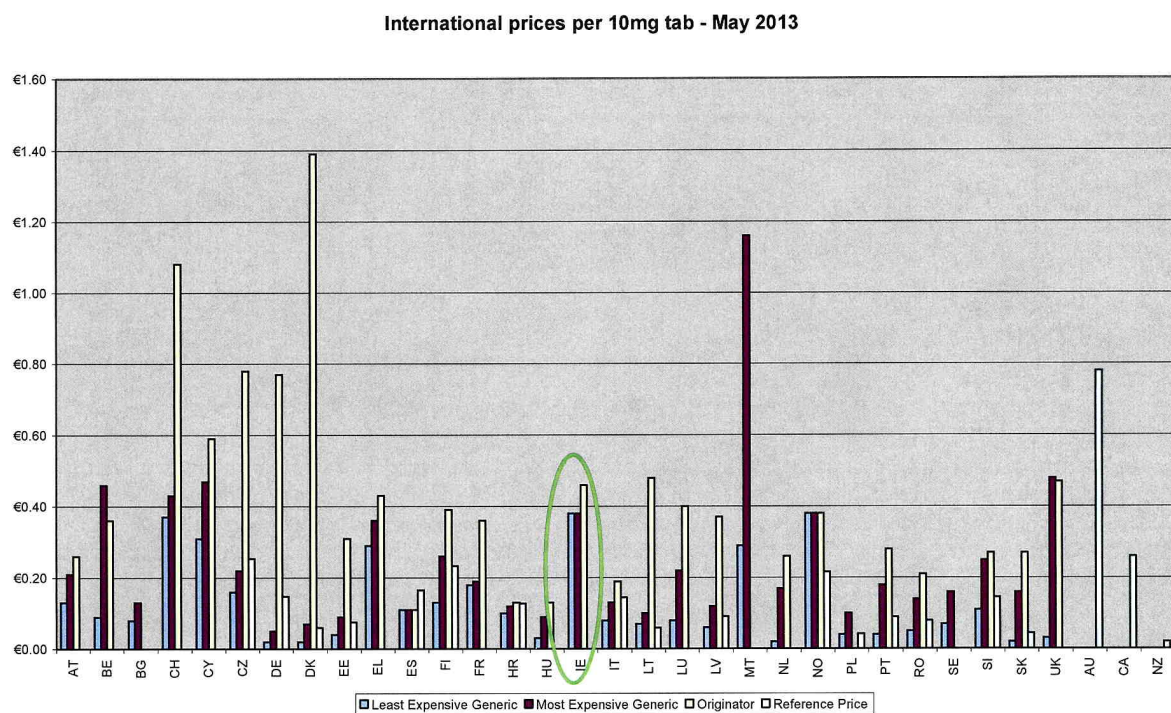


Figure 3: 20mg Atorvastatin International Pricing

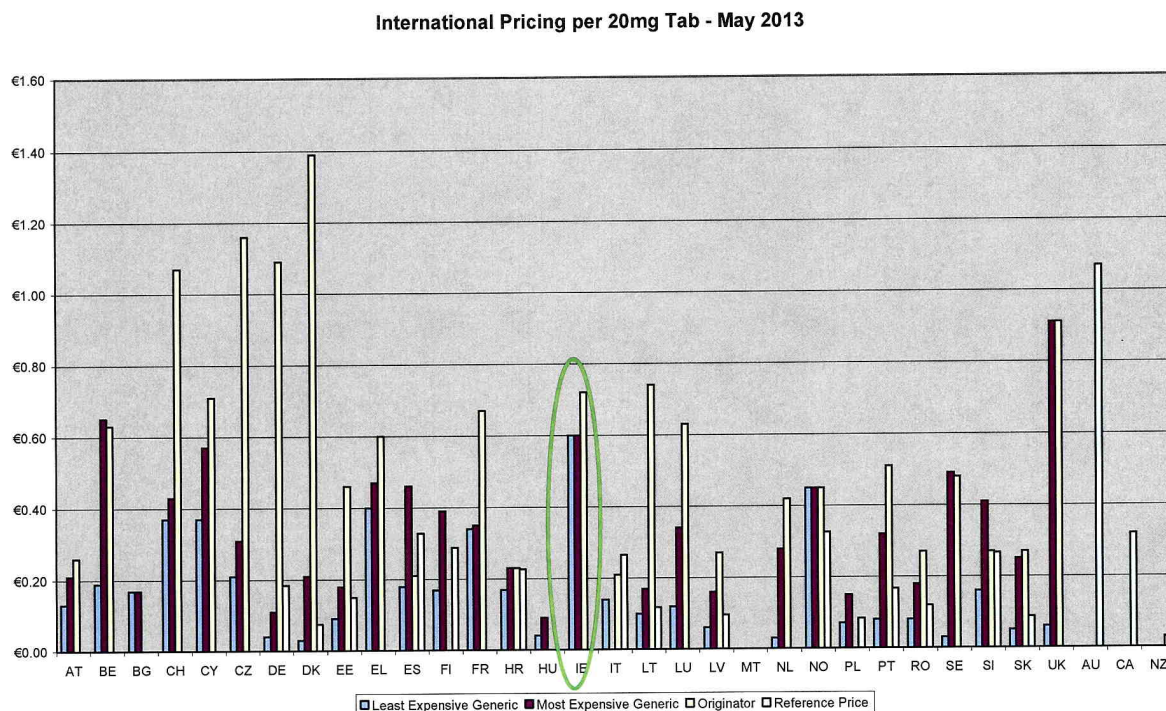
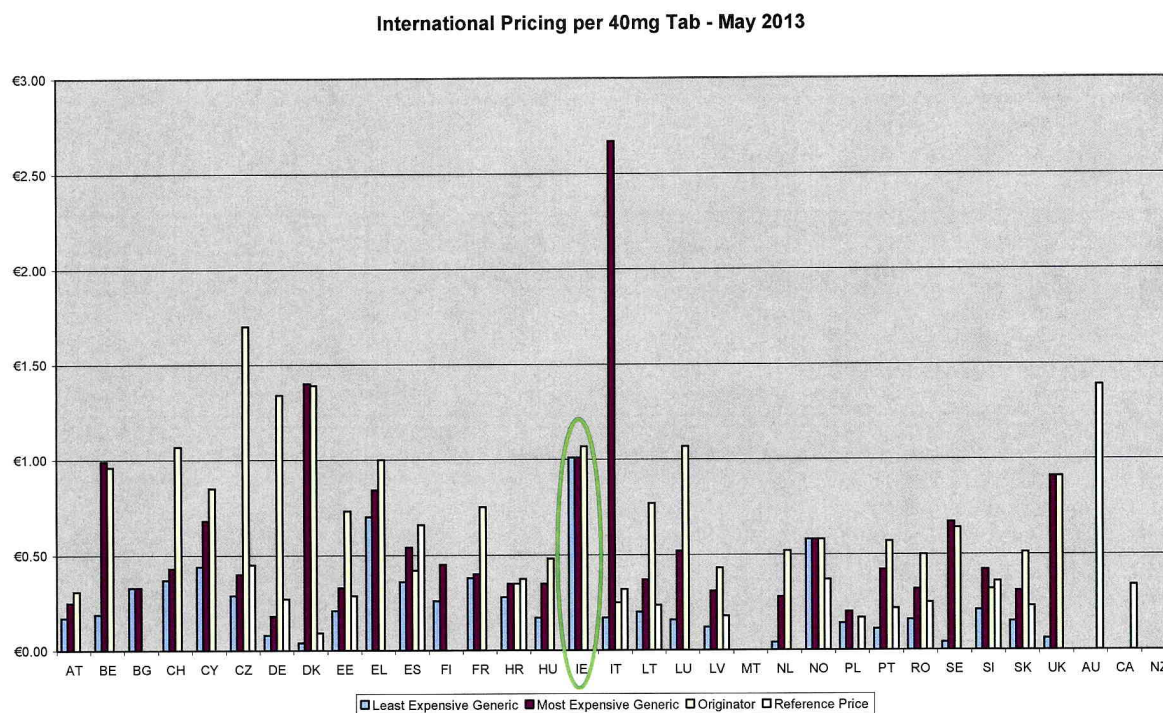


Figure 4: 40mg Atorvastatin International Pricing



Blue text is exact text of the ACT
Black text is HSE understanding as at 20th June 2013

Figure 5: 80mg Atorvastatin International Pricing

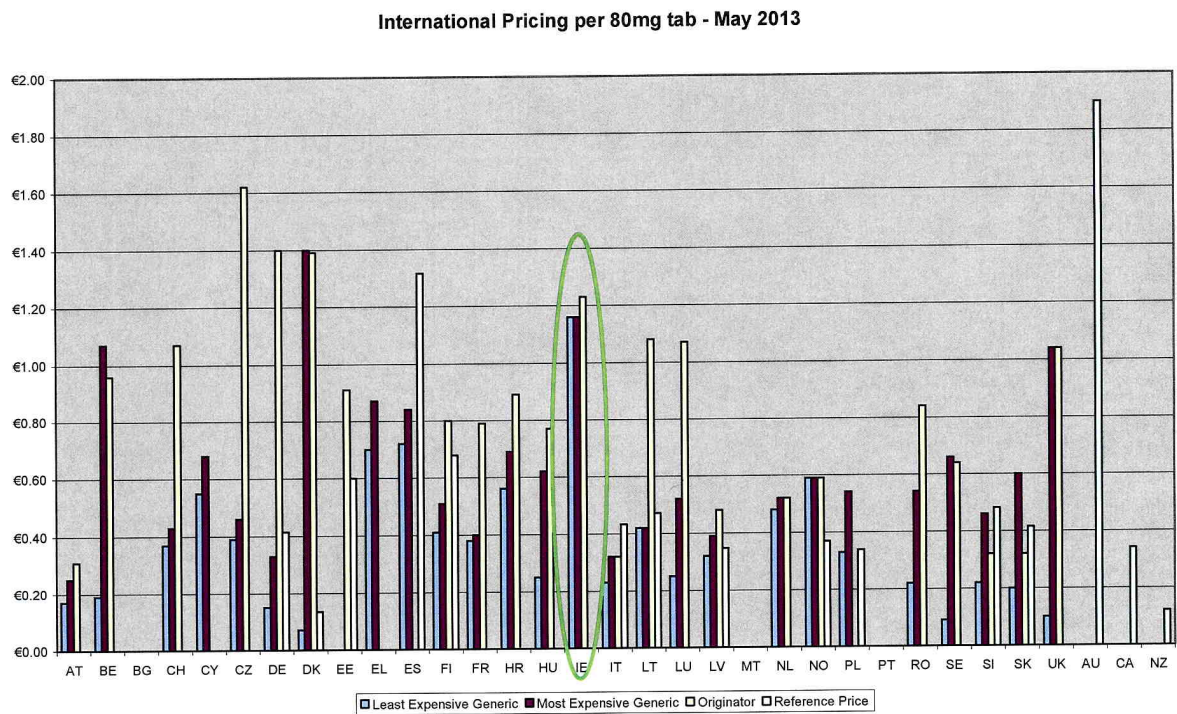


Figure 6: Statin Reimbursement Prices June 2013 (Source: Primary Care Reimbursement Service (PCRS) Database)

