

How Drug Prices Are Set in Ireland

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This note explains the mechanisms to set the price of drugs in Ireland

Policy Context

The increase in the costs of drugs in Ireland and the perception that prices are higher than in other countries has raised concerns about how these prices are set in Ireland.

The importance of the drug pricing mechanism in Ireland is because the State provides free or subsidized drugs to patients under various schemes. The State currently accounts for 85 per cent of overall pharmaceutical expenditure in Ireland, in both the hospital and the community sector and with total pharmaceutical expenditure by the state at €2.5 billion in 2015.

In 2012 Ireland had the third highest per capita expenditure on drugs of all twenty-five countries in the EU for which data was available. It was 43% above the average² While all EU countries have seen substantial increases in drugs costs since the turn of the century, Ireland's increases have been among the sharpest, nearly tripling from 2000 to 2008.

Setting the price³ of new drugs

At present, drug prices are set in negotiations between the State and pharmaceutical representative bodies or trade associations. Agreements between the State and the Irish Pharmaceutical Healthcare Association (IPHA) determine the factors that set the pricing of single source in-patent drugs. These are as follows :

1. The price charged by the patent holder of the new drug in a basket of nine other EU Member States⁴

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² OECD, Health at a Glance Europe 2014 Table 6.4.1.

³ The “price” of a pharmaceutical referred to in this note is the pharmaceutical price at the ex-factory level rather than the retail or pharmacy level. This “ex-factory price” is the base price on which wholesale and pharmacy margins and fees are added in order to determine the price paid by the patient or the State in the State pharmaceutical reimbursement schemes.

⁴ The **basket of nine EU Member States** is made up of: Belgium, Denmark, France, Germany, the Netherlands, Spain, the UK, Finland and Austria. The basket includes countries that tend to have high prices for new drugs such as Germany, and some that tend to have lower prices such as Spain. This is meant to provide a compromise between the State (the buyer), and the IPHA (the seller), as one would

2. A formula for using this price information to set the new drug price in Ireland
3. The frequency with which the price of a new pharmaceutical is realigned
4. A pharmacoeconomic assessment, but only for drugs that are likely to have a significant budgetary impact.

This is referred to as 'external reference pricing' and is the most common method of pricing used across the EU.

Over the past nine years there have been numerous long term and short term agreements as to what factors should determine the price of a new drug. Of these the State/IPHA 2006–2010 agreement forms the longest running basis for the pricing of new pharmaceuticals.

Pricing Parallel Imports

The EU Single Market allows firms, to purchase in-patent and other drugs in Member States with lower prices and resell them in Member States where prices are higher without the permission of the patent holder. Other than packaging, these parallel imports are identical to the patent-owner's brand. Supply is however generally undertaken by specialist firms compliant with regulatory requirements concerning, packaging, labelling, etc.

The price of these parallel imports is not a part of the State/IPHA Agreements. Here the State negotiates an ex-factory price for parallel imports which is at a discount to the price of the new drug.

The patent holder is likely to account for 100 per cent of the market when it first markets its product. In the case of Ireland which is generally an early adopter, the new pharmaceutical will only have limited availability in other countries. Also of importance is that sales volume builds slowly over time in order to reach a level that is large enough for a parallel importer to incur the expenses necessary to enter the market in Ireland.

As the patent holder markets the new drug more widely across lower priced Member States, it will become more profitable for parallel imports to increase. . These parallel imports can be substituted by the pharmacist when presented with a prescription for the brand holder's or originator's product, with no permission required of the patient or the prescriber. Here, although the pharmacist is

prefer a basket of lower-priced countries while the other would prefer a basket of higher-priced countries.

reimbursed on the basis of a price that is set, the parallel importer is able to discount off this price with the difference retained by the pharmacy.

Hence the importance of parallel imports will depend on the price difference between the ex-factory price of the parallel import, compared with the price that the parallel importer actually pays in a lower priced member state such as Spain. The larger the difference in this price the greater the incentive exists for parallel imports. Apart from the discount, the benefit of the remaining price difference accrues to the parallel importer and the pharmacist, not the State.

The Price of New Drugs

Single source in-patent pharmaceuticals

In the case of new drugs patented by a single manufacturer, the only competition is from parallel imports. This means that the ex-factory price paid for these drugs is the weighted average of the patent-holder's ex-factory price and that of each of the parallel importers, where the weights are the quantity supplied.

In summary the ex-factory price of a new drug depends on the share of the new drug supplied by the patent holder, the price of the patent holder as determined through the external reference pricing mechanism, the market share of the new drug supplied by parallel importers, and the price of parallel imports.

Setting the price of multiple source off-patent drugs (Generics)

Setting the price of drugs for which the patent has expired and for which there is generic competition requires agreement not only between the State and the IPHA, but also between the State and the representative body of the generic pharmaceutical manufacturers, the Association of Pharmaceutical Manufacturers of Ireland (APMI).

In addition, where the Irish Medicines Board (IMB) designates a group of pharmaceuticals as interchangeable, then the ex-factory price declines to 40 per cent of the patent-holder's price prior to generic entry.

If the pharmaceutical patent is no longer valid, the patent holder can no longer prohibit new entrants to the market, this is a situation of **multiple source off-patent drugs** which are usually referred to as generics. In this case the ex-factory price paid for the drugs will be the weighted average of the patent owner's ex-factory price and that of each of the generic manufacturers. Generic manufacturers will be bigger suppliers in high-volume pharmaceutical markets and generally charge a lower ex-factory price than the patent holder.

Once a patent expires and generic manufacturers can enter the market, there is provision for the price charged by the patent holder to fall.

The price of generics has declined over time relative to the price of the patented drugs. The discount has widened from 35 per cent before 2010 to between 50 and 60 per cent now.

The critical factor in determining the generic/patent-holder price difference is whether or not the drug is part of an interchangeable pharmaceutical group. When the pharmaceutical is part of an interchangeable pharmaceutical group, the generic price will be 20 per cent less than the patent-holder's ex-factory price. In all other cases the difference in ex-factory price will be small (5 per cent) or substantial, but temporary (29 per cent for a year, 5 per cent subsequently).

Therefore as the number of interchangeable pharmaceutical groups is expected to increase in the future, overall generic prices should fall relative to those of patent drugs. If not determined as interchangeable, then differences in generic and patent- prices will be substantial, but temporary, i.e., apart from the first year in which the generic enters the market, the difference will be five per cent.

The frequency with which the price of the new drug is realigned.

The initial price of a new drug can only reflect the average of those countries of the nine where the drug is currently marketed on the date at which the patent holder applies to the HSE for the drug to be listed for reimbursement purposes under one of the State pharmaceutical reimbursement schemes. However, as the new drug is marketed by the patent holder in the remaining Member States, then the price of the drug can be recalculated to reflect its wider availability. Hence the drug price is likely to be high, initially at least. The rationale however is that this price is likely to fall through time as the drug becomes available in the more lower-priced countries such as Spain. Thus, once the new drug is marketed across the other nine countries the drug price in Ireland should be realigned to reflect its wider availability in other, often lower priced countries. Recent evidence suggests, however, that compared to other European countries the prices of new drugs in Ireland are realigned considerably less frequently.²

In fact, on the whole, the evidence seems to suggest that drugs tend to be launched early in Ireland, such that most new drugs are only available in the Member States of a small number of early adopters of new drugs – Denmark, Germany, and the UK – that have free or unregulated pricing and as a result relatively high prices and that following this there is only limited realignment.^{11, 12}

A pharmacoeconomic assessment

The final determinant in the price of a new drug is a ***pharmacoeconomic assessment***. A pharmacoeconomic assessment must occur when⁵, a drug 'may be high cost or have a significant budget impact on the Irish healthcare system'. If this assessment determines that the price is too high, negotiations take place between the State and the pharmaceutical manufacturer to reach a mutually acceptable price consistent with the value ascribed in this pharmacoeconomic assessment. Pharmacoeconomic assessments are conducted by the National Centre for Pharmacoeconomics (NCPE).¹⁴ If, the recommendations of this pharmacoeconomic assessment are not carried out then the justifications for this must be given clearly. In this way, it is simpler for decisions to be consistent with the results of this assessment and less likely to be determined or influenced by interested parties such as patient advocacy groups, manufacturers or others.

Setting the price of multiple source off-patent pharmaceuticals

In the case of drugs for which the patent has expired and for which there is generic competition, agreement must take place not only between the State and the IPHA, but also between the State and the representative body of the generic pharmaceutical manufacturers, the Association of Pharmaceutical Manufacturers of Ireland (APMI).

Two key features of these agreements are that the ex-factory price-setting mechanisms under these agreements follow the same procedure regardless of the type of drug and that a single maximum ex-factory price across hospital and community supply is set.

The price charged by the patent holder and the price charged by the generic manufacturer are linked to the price of the patent holder prior to the entry of the generic manufacturer. In other words, the external reference price is the benchmark from which multiple source off-patent pharmaceutical prices are discounted.

The State/IPHA Agreements

Once a patent expires and generic manufacturer can enter the market there is provision for the price charged by the patent holder to change, this is determined under a succession of agreements between the State and the IPHA.(See Table 1)

TABLE 1 Setting the Patent-Holder's Price for Off-Patent Pharmaceuticals with Generic Competition,^a
Price Agreements between the State and the IPHA, 2006–2015

⁵ clause 4.3 of the 2006–2010 State/IPHA Agreement

Agreement Duration (State Signatories)	Pricing Principles
01/09/06–31/08/10 (HSE)	<p>First stage: six months following the commencement of the State/IPHA Agreement a 20% reduction off the pre-entry price of the patent holder after generic competition first appeared.</p> <p>Second stage: 22 months after first stage price reduction, a further 15% reduction off the pre-entry price of the patent holder. Total price reduction off the patent-holder's price^b prior to the entry of the generic, 35%.</p>
01/02/10–01/03/12 (HSE)	<p>For pharmaceuticals where the price reductions were completed under the 2006–2010 State/IPHA Agreement by 1/2/10, prices reduced by an additional 40%. Total price reduction off the patent-holder's price^b prior to entry of the generic, 61%.^c</p> <p>For pharmaceuticals where the first stage price reductions under the 2006–2010 State/IPHA Agreement had been made by 1/2/10, prices were reduced by 40 per cent, the subsequent second stage reduction was 9% of the patent-holder's price prior to the entry of the generic. Total price reduction off the patent-holder's price^b prior to the entry of the generic, 61%.^d</p> <p>For pharmaceuticals that experience generic competition after 1/2/2010, price reductions were in accordance with the pricing principles under the 2006–2010 State/IPHA Agreement.</p>
18/06/12–31/10/12 (DoH)	<p>For pharmaceuticals that are about to or have experienced the first stage price reductions under the 2006–2010 State/IPHA Agreement by 18/06/12, an immediate reduction by a further 10%. Total price reduction off the patent-holder's price^b prior to the entry of the generic, 30%.</p>
1/11/12–31/10/15 (DoH and HSE)	<p>For pharmaceuticals where the price reduction is less than 40%, on 1 November 2012 there will be a price reduction to 60% of the patent-holder's price^b prior to the entry of the generic; twelve months later there will be an additional 10% reduction. Total price reduction off the patent-holder's price^b prior to the entry of the generic of 50%.</p> <p>For pharmaceuticals that experience generic competition after 1/11/12. First stage, immediate price reduction of 30%; second stage, twelve months a further 20% price reduction. Total price reduction off the patent-holder's price^b prior to generic competition, 50%.</p>

Notes: a The table refers to pharmaceuticals which are off-patent (i.e., the patent has expired) and where the identical pharmaceutical form of that pharmaceutical is approved by the Irish Medicines Board or the European Commission and is available for prescription under State schemes, State-funded hospitals and State agencies which normally include the provision of pharmaceuticals. A pharmaceutical meeting these criteria is referred to as experiencing generic competition.

b The patent-holder's price would be set in accordance with the pricing rules for new pharmaceutical.

c Under the 2006–2010 State/IPHA Agreement the price reduction was 35%. If the patent holder's price prior to the entry of the generic was 100 then the price was reduced to 65. 40% of 65 is 26, so that the price is now 39 or a reduction of 61% compared to the patent holder's price prior to the entry of the generic.

d Under the 2006–2010 State/IPHA Agreement the first stage price reduction was 20%. If the patent holder's price prior to generic entry was 100, then the price was reduced to 80. 40% of 80 is 32 so the price now falls to 48. The second stage price reduction of 9 per cent off the pre-entry patent holder's price results in a price of 39, so that the price is now 39 or a reduction of 61% compared to the patent holder's price prior to the entry of the generic.

Source: Brick, A., Gorecki, P. K., & Nolan, A. (2013). Ireland: pharmaceutical prices, prescribing practices and usage of generics in a comparative context. Economic and Social Research Institute (ESRI) Research Series.

The State/APMI Agreements

Agreements between the State and APMI mirror what we have seen above. The standard approach taken is for the State to reach an agreement with the IPHA first and then to make an agreement with the APMI. For multiple off-patent pharmaceuticals the maximum price for generic manufacturers is set in relation to the price of the patent holder prior to the entry of the generic.

These pricing agreements are complex as is seen from the actual pricing agreements in Table 2 below. The evidence suggests that the price of generic manufacturers has declined over time relative to the price of the patent holder or originator prior to generic entry. Under the 2006–2010 State/APMI Agreement, the price of generic manufacturers was discounted by 35 per cent relative to the patent-holder's price prior to entry. By the 2012–2015 State/APMI Agreement this number had reached between 50 and 60 per cent.

TABLE 2 Setting the Generic Price for Off-Patent Pharmaceuticals with Generic Competition,^a Price Agreements between the State and the APMI, 2006–2015

Agreement Duration (State Signatories)	Pricing Principles
10/09/06–09/09/10 (HSE)	There is no reference in the 2006–2010 State/APMI Agreement to the price charged by generic manufacturers. It appears that the ex-factory price for a generic manufacturer is the same as the patent-holder's price for multiple source off-patent pharmaceuticals as set out in the 2006–2010 State/IPHA Agreement. (Details are provided in Table 3.3 and Figure 3.3.) In other words, the generic manufacturer and the patent holder have the same ex-factory price for multiple source off-patent pharmaceuticals.
01/10/10–01/03/12 ^b (HSE)	Effective 1 October 2010: APMI members' <i>existing</i> generic prices will be at least 2% lower than the price of the patent holder for the equivalent pharmaceutical; APMI members' <i>new</i> generic products, where the patent has expired after 1 February 2010, will be at least 5.6% lower than the price of the patent holder for the equivalent pharmaceutical.
1/11/2012–2015 (DoH and HSE)	On 1 November 2012 the price of generic products were reduced to 50 per cent of the patent-holder's price prior to the entry of the generic. ^c On implementation of the Health (Pricing and Supply of Medical Goods) Act 2013, generic products included <i>in</i> interchangeable pharmaceutical groups will be reduced by at least 60% of the patent-holder's price prior to the entry of the generic. ^c On implementation of the Health (Pricing and Supply of Medical Goods) Act 2013, generic products <i>not</i> included in interchangeable pharmaceutical groups will be reduced by at least 52.5% of the patent-holder's price prior to the entry of the generic. ^c The price of all <i>new</i> generic products will initially be set to at least 50% of the patent-holder's price prior to the entry of the generic. If included in an interchangeable group, these new generic products will be reduced by at least 60% of the patent-holder's price prior to the entry of the generic. ^c If not included in an interchangeable group these new generic products will be reduced by at least 52.5% of the patent-holder's price prior to the entry of the generic, when the price of the patent-holder price is reduced to 50% of the price prior to the entry of the generic. ^c

- Notes:*
- A The table refers to pharmaceuticals which are off-patent (i.e., the patent has expired) and where the identical pharmaceutical form of that pharmaceutical is approved by the Irish Medicines Board or the European Commission and is available for prescription under State schemes, from State-funded hospitals or State agencies pharmaceuticals. A pharmaceutical meeting this criterion is referred to as experiencing generic competition.
 - B In December 2010 the State reached an agreement with IPHA that led to reduction in the price of number of pharmaceuticals from January 2011. The APMI initiated equivalent price reductions, but not until August 2011. (Hence the generic price for a period in 2011 exceeded the patent holder's for the equivalent pharmaceutical.) However, if the price reduction by the APMI member necessary to match the patent-holder's price reduction was greater than 30% and made the APMI member's product non-viable, a review mechanism was set up that could result in the generic price exceeding the patent-holder's price for an equivalent pharmaceutical. This was only permitted in exceptional circumstances.
 - C The patent-holder's price would be set in accordance with the pricing rules for new pharmaceuticals.
- Source:* Brick, A., Gorecki, P. K., & Nolan, A. (2013). Ireland: pharmaceutical prices, prescribing practices and usage of generics in a comparative context. Economic and Social Research Institute (ESRI) Research Series.

Without the entry of generic manufacturers, a patent holder will capture 100 per cent of the market. Certain regulatory and other requirements are necessary for a generic manufacturer to enter the market. However these are significantly less stringent than those the patent holder would have meet when first coming to market. As such the generic manufacturer will likely have costs that are substantially below those of the patent holder.

Costs are also likely to be below the ex-factory price of multiple-source pharmaceuticals as set by the agreements between the State and the APMI for the generic manufacturer.^{16, 17}

Similar to the situation of parallel importers, the existence of generic manufacturers drives a wedge between the price at which the pharmacist is reimbursed and the price paid to the generic manufacturer. As of the Health (Pricing and Supply of Medical Goods) Act of 2013, pharmacists can substitute generic pharmaceuticals for the patent-holder's pharmaceutical. It appears that growing acceptance of generic manufacturers by the public has meant that pharmacists have dispensed increased volumes of pharmaceuticals of generic manufacturers, reaching in 2012, 70 per cent of one pharmaceutical.^{2, 17, 18}

Conclusion

The price of new drugs and multiple source off-patent drug prices is primarily determined by the price of the patent holder as determined by the use of a basket of nine Member States. The price will initially tend to be based on higher-priced countries and will fall more slowly due to the timing of the realignment of prices as the drug becomes available in more countries in the basket of nine used

to set the price of new drugs in Ireland. Furthermore, of course, there is no guaranteed further readjustment of new drug prices.

The price of multiple source off-patent drugs in Ireland is linked to the patent-holder's price prior to entry and, as we can expect this price to be high by EU standards, we can expect that the price of multiple source off-patent pharmaceuticals will also be high.

The State has introduced a series of reforms since the mid-2000s designed to reduce drug prices and expenditure. Retail and pharmacy mark-ups were reduced while wholesale mark-ups fell by as much as 50%, ex-factory prices are being benchmarked against lower priced Member States, better information has been provided to prescribers and the price of generic drugs has fallen faster and further.

The Health (Pricing and Medical Goods) Act 2013 provides a radical structural change in the way in which drug pricing takes place in Ireland with consequent benefits for the cash-paying patient and the taxpayer. This Act contains a series of factors that give the HSE a wide price setting discretion. Central to this is that for the first time, for interchangeable pharmaceutical products, pharmacists are also be able to select a lower priced pharmaceutical product than that prescribed for the patient by a medical practitioner.

Further initiatives to reduce costs include promoting increased use of generics better prescribing patterns, strengthening price transparency at the retail level to ensure that patients are well-informed and measures taken to ensure that pharmacists have both the ability and the incentive to provide such information.

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